ASSEMBLEIA DA REPÚBLICA

COMMITTEE FOR CONSTITUTIONAL AFFAIRS, RIGHTS, FREEDOMS AND GUARANTEES

REPORT

COM (2012) 548 final – PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 273/2004 on drug precursors

1 – Introduction

The above European initiative was referred to the Committee for Constitutional Affairs, Rights, Freedoms and Guarantees for the purposes of the monitoring, examination and issuing of opinions by the Assembly of the Portuguese Republic as part of the process of the integration of the European Union (EU). By amending Regulation (EC) No 273/2004, this initiative responds to the recommendation contained in the Commission report that the prevention of the diversion from EU-internal trade of AA (acetic anhydride, the main drug precursor for the production of heroin) be improved by extending the registration requirement (hitherto applicable only to operators placing AA on the market) to include users of this substance and by enhancing the harmonised registration provisions, which would contribute to fairer conditions that would preserve the internal market and avoid the adoption of divergent national measures.

2 - Objectives and content of the proposal

It should be understood that trade in drug precursors is not, in itself, forbidden; it brings benefits. In order to prevent precursors being diverted to illicit drug production, a specific regulatory framework has been set up at international and Community level, which has created a partnership between the industry and the authorities.

A loophole has, however, been detected in the legal system in question: large quantities of acetic anhydride ('AA') have been diverted from EU-internal trade: 75% of worldwide seizures of AA in 2008 were made in the EU.

The problem of crime is compounded by the serious public health problem in Europe associated with heroin consumption.

By amending Regulation (EC) No 273/2004, this proposal addresses the recommendation in the Commission Report that the prevention of the diversion of AA from EU-internal trade be improved by extending the registration requirement (which hitherto applied only to operators placing AA on the market) to users of the substance and, by enhancing the harmonised registration provisions, which would contribute to fairer conditions that would preserve the internal market and avoid the adoption of divergent national measures.

3 - Legal basis.

The legal basis of the proposal is Article 114 of the Treaty on the Functioning of the European Union (TFEU). The purpose of this article is to establish an internal market while ensuring a high level of protection of human health and the environment.

4 - Principle of subsidiarity

Under the principle of subsidiarity, the European Union may not take action in areas which do not fall within its exclusive competence unless '*the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level*' (Article 5(3) of the Treaty on European Union).

The proposal states that it upholds the principle of subsidiarity, based on the idea that the objectives of the proposed Regulation are 'effective' and 'harmonious'.

It recalls, however, that some Member States take the view that they are legally prevented from adopting national control measures going beyond the EU legislation on the basis of Article 10 of Regulation (EC) No 273/2004, which empowers Member States to adopt such national measures as are necessary to enable the competent authorities to perform their monitoring and surveillance duties. They argue that the fact that EU legislation subjects only *operators* to control measures (no obligations are imposed on end users) should be understood as a deliberate and binding decision by the EU-legislator that end users should not be subject to the control of the drug precursor legislation.

5 - Opinion of the Rapporteur

It is understandable that a proposal like this invoke the need for 'harmony' and 'effectiveness'. Simply put, the rapporteur finds no legal basis other than this proposal that would bind the Member States in terms of the internal policies they adopt to control psychotropic substances at end-user level.

Strictly speaking, it is too easy to cite 'greater effectiveness' or greater 'harmony' when this is not borne out in substance, to disregard the fact that the Union still respects the Member States' national identities, 'inherent in their fundamental structures, political and constitutional' (Article 4(2) TEU) and that the delimitation of competences is not solely a matter of *subsidiarity*, but upholds the *principle of conferral* (Article 5(1), i.e. the European Union shall act only within the limits of the competences conferred upon it by the Member States in the Treaties to attain the objectives set out therein (Article 5(2).

It is easy to see that the legal basis advanced for the proposal was not sound. After all, applying the same logic, 'establishing an internal market while ensuring a high level of protection of human health and the environment' would, for example, permit the EU to legislate on measures to contain smoking, on the same grounds as advanced in this explanatory memorandum, i.e. stating the number of illnesses and deaths directly caused by the direct or indirect ingestion of smoke.

Would the same rule of competence not apply in that case? Is this not a question of 'human health'? Likewise, is it not more 'effective' and more 'harmonious' for the Member States not to adopt divergent measures?

Any number of examples could demonstrate that Article 8(4) of the Constitution of the Portuguese Republic recognises the primacy of all Community law (academic writings reflect several trends in this regard: unlimited acceptance of primacy (FREITAS DO AMARAL); recognition of the primacy of the Constitution (MIGUEL GALVÃO TELLES, BLANCO DE MORAIS); recognition of primacy in application (GOMES CANOTILHO, VITAL MOREIRA and JÓNATAS MACHADO), but national sovereignty is upheld (see its well-known concluding formula).

The principle of subsidiarity is in some way related to the principle of State sovereignty. What cannot be sufficiently achieved by the Member States is delegated to the EU. But that delegation implies that the supreme competence – the principle of national sovereignty or national independence – is, by treaty, freely and clearly shared with or delegated to the Union.

The objective of monitoring users of AA does not, in the rapporteur's opinion, fall under the jurisdiction of the European Parliament and the Council; on the contrary, in the areas of policy on crime, offences, public health and rights, freedoms and guarantees, it remains within the competence of each Member State.

6- Opinion

In the light of the foregoing, the Committee for Constitutional Affairs, Rights, Freedoms and Guarantees is of the opinion that COM (2012) 548 final – PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL Amending Regulation (EC) No 273/2004 on drug precursors complies with the principle of subsidiarity**.**

This report should be sent to the European Affairs Committee.

Palácio de São Bento, 10 December 2012

Rapporteur,	**Chairman of the Committee**
(Isabel Moreira)	**(Fernando Negrão)**

Opinion

COM (2012) 521 Final

Proposal for a REGULATION 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

COM (2012) 548 Final

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL Amending Regulation (EC) No 273/2004 on drug precursors

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PART 1 – INTRODUCTORY NOTE

Pursuant to Article 7 of Law No 43/2006 of 25 August 2006 regulating the monitoring, examination and issuing of opinions by the Assembly of the Portuguese Republic as part of the process of the integration of the European Union, the Proposal for a REGULATION 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 and the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 273/2004 on drug precursors were referred to the Committee on Health.

Given the subject, it falls to Parliament's Committee on Health to analyse the proposals and draft the respective report.

PART II – 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 regional and global markets, but some of them can also be diverted from the licit distribution channels for the illicit manufacture of narcotic drugs.

Bearing in mind the wide range of legitimate uses of drug precursors, their trade cannot be banned, and controlling drug precursors is therefore a key to the fight against narcotic drugs. A specific regulatory framework, both at international and at EU level, has been put in place to monitor legal trade in these and to identify suspicious transactions, thus preventing their diversion for illicit use.

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[1]. While ephedrine and pseudoephedrine are controlled at international and EU level, the medicinal products containing them are not monitored when they are exported from or transit through the Union customs territory and they are therefore targeted by drug traffickers as a source of precursors for the illicit manufacture of methamphetamine, given that the ephedrine or pseudoephedrine contained in these products can be easily extracted using cheap home-made equipment and through a simple chemical process. These products are specifically targeted by drug traffickers as a source of precursors for the illicit manufacture of methamphetamine.

The fact that medicinal products for human use containing ephedrine or pseudoephedrine are excluded from the provisions of Regulation (EC) 11/2005, which applies to trade in drug precursors between the EU and third countries, has led to a situation where these products could not be stopped or seized by Member States' competent authorities when exported from or transiting through the Union customs territory, even though it is known that they may be misused for the illicit manufacture of methamphetamine in their country of destination.

Because the EU is criticised internationally for not taking adequate customs control measures in the different Member States, it is seeking to close the loophole in the current legislation with regard to the powers vested in the customs and police, who can intercept and seize ephedrine and pseudoephedrine but may not intercept and seize medicinal products containing those same substances.

Methamphetamine is a synthetic drug which belongs to the amphetamines group. This drug manipulates pleasure centres of the brain, can be more potent than cocaine and usually has a longer-lasting effect. Taken as pills, smoked, inhaled or injected, it is particularly attractive to young people because it produces a sense of high energy, a release of social inhibitions and feelings of cleverness, competence and power. The physical and psychological effects (feelings of anxiety, hyper stimulation and paranoia) occur rapidly.

Scale of the problem

Between 2004 and 2009 the quantities of methamphetamine seized increased, as did the number of seizures, and this is a sign that the markets may be expanding in Europe. Worldwide, North America accounted for nearly half of global seizures of this drug.

After the continued increase of seizures of medicinal products from 2007 to 2009, the total amount seized worldwide decreased in 2010. However, these fluctuations in seizures reveal only that illicit manufacture is taking place in a given part of the world and that the absence of a control mechanism for medicinal products containing these substances remains a concern both at European and at global level.

These initiatives should therefore function as a deterrent, requiring specific monitoring by the EU so as to prevent the illicit diversion of drug precursors.

Consistency with other EU policies

In line with the *EU Drugs Strategy (2005-2012),* which provides for the adoption of measures intended to reduce the supply of precursors and thus to reduce the production of drugs, the aim is to prevent, effectively, the diversion of medicinal products containing precursors to the illicit manufacture of drugs.

The trade in medicinal products containing drug precursors is regulated by Directive 2001/83/EC, although it pursues a different objective, in that it seeks only to protect public health by controlling the production, distribution and use of medicinal products in order to ensure their quality, safety and efficacy.

The medicinal products legislation has recently been amended by Directive 2011/62/EU with the aim of preventing the entry into the legal supply chain of falsified medicinal products.

In the analysis under way, however, and given that the main question relating to drug precursors is the risk of these products leaving the legal supply chain, it is improbable that these provisions will make a significant contribution to solving the problem.

Impact Assessment:

The impact assessment report drawn up on this subject identified and assessed policy options aiming to prevent the diversion of medicinal products containing precursors to the illicit manufacture of methamphetamine by introducing control measures over these products when traded between the Union and third countries while maintaining their free flow. Among the options analysed, (1-not taking new legislative action; 2- recommending voluntary measures to the Member States; 3 - increasing the powers of the competent authorities; 4 - increasing the powers

of competent authorities and introducing the use of pre-export notifications; 5 – making medicinal products containing ephedrine and pseudoephedrine subject to the same control requirements as ephedrine and pseudoephedrine; 6 – banning the trade in medicinal products containing ephedrine and pseudoephedrine) the impact assessment report concluded that, strategically, the problem would be better solved by compulsory control measures, granting the competent authorities powers to intercept and/or seize medicinal products containing precursors when exported from or transiting through the customs territory of the Union so as to reduce the diversion of these products and thus to limit the illicit production of methamphetamine (option 4). The view taken was that this option would also be the most appropriate in that it would provide for a legal basis, would impose only one extra control requirement and would not generate additional administrative burdens.

The underlying drivers of this problem may thus be summarised as follows:

⇒ The control measures over ephedrine and pseudoephedrine have been strengthened worldwide, and some countries have gone so far as to ban the import of these substances;

⇒ Traffickers therefore needed to look for alternative sources of ephedrine and pseudoephedrine to manufacture methamphetamines, targeting medicinal products containing these substances which are not subject to strict control measures;

⇒ Measures to control and prohibit the entry of medicinal products containing ephedrine and pseudoephedrine were strengthened in other parts of the world, and traffickers therefore turned to the regions of the EU where the control measures in relation to these medicinal products are less tight.

In the light of the provisions, the following questions should be raised:

a) Legal basis

Concerning the grounds for the issue under examination, the legal basis is Article 207 of the Treaty on the Functioning of the European Union (TFEU), which defines the EU's common commercial policy.

b) Principle of subsidiarity

In the initiatives under consideration the principle of subsidiarity does not apply, given that the issue under analysis (the common commercial policy) falls under the exclusive competence of the

European Union, as laid down in Article 3(1) of the Treaty on the Functioning of the European Union.

c) Content of the initiative

The overall objective of these initiatives is to enshrine a policy of effective prevention of the deviation of drug precursors for the illicit manufacture of drugs.

It therefore seeks to regulate the external trade in medicinal products containing ephedrine and pseudoephedrine and thus to contribute to the worldwide fight against illegal drug manufacture and to combat the illicit manufacture of methamphetamine by controlling the supply of substances contained in medicinal products that are exported, imported or that transit between the EU and third countries, preventing them being diverted without compromising legal trade in these products for legitimate ends, avoiding disproportionate administrative burdens for national authorities and for the industry involved in the trade in medicinal product containing those same substances.

d) Budgetary impact

These initiatives will not have an impact on human resources or on the budget of the European Union.

PART III CONCLUSIONS

1. In the initiatives under consideration the principle of subsidiarity does not apply, given that the issue under analysis falls under the exclusive competence of the European Union.
2. Pursuant to Law No 43/2006 of 25 August 2006, and for due effect, this report should be referred to the European Affairs Committee.

Palácio de São Bento, 16 November 2012

Rapporteur **President of the Committee**

(Elza Pais) **(Maria Antónia Almeida Santos)**