COUNCIL OF THE EUROPEAN UNION

Brussels, 3 October 2012

14394/12 ADD1

Interinstitutional File: 2012/0250 (COD)

UD 237
ENT 226
CORDROGUE 63
CODEC 2265

COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	27 September 2012
to:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No Cion doc.:	SWD(2012) 267 final
Subject:	COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT Accompanying the document 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

Delegations will find attached Commission document SWD(2012) 267 final.

Encl.: SWD(2012) 267 final

EUROPEAN COMMISSION

Brussels, 27.9.2012
SWD(2012) 267 final

COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

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) 521 final}
{SWD(2012) 268 final}

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1. PROBLEM DEFINITION

1.1. What is the problem?

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. In order to prevent their diversion from legal trade to illicit drug production a specific regulatory framework has been set up (both on international level[1] and in the EU[2]) in order to identify suspicious transactions. However, this is not the case for medicinal products containing ephedrine or pseudoephedrine. As the ephedrine and pseudoephedrine contained in medicinal products can be easily extracted (by 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) 111/2005, which applies to trade 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 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. The EU is expected to close the loophole in the current legislation as regards the powers conferred to customs and police authorities who can stop and seize ephedrine and pseudoephedrine but cannot stop and seize medicinal products containing ephedrine or pseudoephedrine.

The underlying drivers of the problem can be summarised as follows:

- the control measures over ephedrine and pseudoephedrine (the substances) have been strenghtened worlwide. Some countries of the world have gone to the extent to prohibit the imports of these substances.

- therefore, the need for traffickers to look for alternative sources of ephedrine and pseudoephedrine to manufacture methampethamines;

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[1] United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, available at: HTTP://WWW.INCB.ORG/PDF/E/CONV/1988_CONVENTION_EN.PDF

[2] Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 and to Article 32 of Council Regulation (EC) No 111/2005 on the implementation and functioning of the Community legislation on monitoring and control of trade in drug precursors

- as a result, traffickers are targeting medicinal products containing these substances which are not subject to strict control measures; and

- the strenghtening of control measures over these medicinal products containing ephedrine and pseudoephedrine in other regions of the world. As a reaction, traffickers target those regions where there are less control measures over these products, when exported or in transit, such as the EU.

From 2007 until 2010, seizures of methamphetamine precursors contained in medicinal products containing ephedrine or pseudoephedrine by EU Member States' competent authorities at the borders have fluctuated considerably. While in 2007 hardly any medicinal products were recorded out of the overall quantities seized (0.3 mt[3] out of 8 mt), in 2008 and 2009 the amount of medicinal products out of the total quantities seized increased sharply (respectively 1.8 mt out of 3.5 mt and 0.6 mt out of 1.4 mt). Even though this amount decreased considerably in 2010 (0.1 mt out of 2.9 mt), many Member States and the International Narcotics Control Board (INCB) are concerned that the mechanisms of Regulation (EC) No 111/2005 for the control of medicinal products containing ephedrine or pseudoephedrine are not sufficient.

1.2. Who is affected

- Third countries, where methamphetamine are produced, whose control measures over medicinal products containing drug precursors are not effective if not reciprocated by exporting and transiting countries;

- Manufacturers and distributors located either inside or outside of the Union, as suppliers or traders of these medicinal products containing ephedrine and pseudoephedrine; and

- Customs authorities, police and health authorities, as the enforcement authorities designated within each Member State to implement the drug precursors legislation.

2. ANALYSIS OF SUBSIDIARITY

Regulation (EC) No 111/2005 is based on Article 207 TFEU (formerly Article 133 TEC). It lays down rules for the monitoring of trade between the Community and third countries in drug precursors.

Currently EU Member States customs authorities seize medicinal products containing ephedrine or pseudoephedrine on the basis of national anti-drugs laws or of the customs code, resulting in different control actions at the EU external borders. Moreover, they try to curtail the diversion of these medicinal products through different types of national measures, thus leading to differing legal requirements for EU economic operators.

3. OBJECTIVES

General policy objectives

- To contribute to the world-wide combat against the illicit manufacture of drugs.

[3] Mt= metric ton = 1000 kg.

Specific policy objectives

- To fight the illicit manufacture of methamphetamine, by controlling the supply of ephedrine/pseudoephedrine contained in medicinal products that are exported, imported or transiting between the Union and third countries through preventing their diversion, while not hampering legitimate trade in these products;

- To maintain the free flow of medicinal products containing ephedrine or pseudoephedrine for legitimate purposes between the Union and third countries;

- To avoid disproportionate administrative burdens on national competent authorities (customs, police, health) and on the industry involved in the trade of medicines containing ephedrine/pseudoephedrine.

Operational objective

To achieve and maintain a downward trend of diversion attempts of medicinal products containing ephedrine or pseudoephedrine, intended for illegal purposes.

4. POLICY OPTIONS

Option 1: taking no new legislative action (baseline option)

Regulation (EC) No 111/2005 will not be modified. Under this Regulation medicinal products containing ephedrine or pseudoephedrine are not controlled. Therefore, Member States' authorities cannot stop or seize these products when they enter or leave the Union customs territory based on EU legislation, even though it is likely that they would be misused for the illicit manufacture of methamphetamine.

Option 2: Recommending voluntary measures to Member States

The Commission would make a Recommendation listing a number of measures for the control of medicinal products containing ephedrine and pseudo-ephedrine from which each Member State can "pick and choose" as they deem it appropriate.

Option 3: Increasing the powers of competent authorities

Medicinal products containing ephedrine or pseudo-ephedrine would be covered by the provisions of Article 26 of the current Regulation (Powers of competent authorities). This would enable EU competent authorities to stop transactions involving these medicinal products when there are reasonable grounds for suspecting that these products might be misused in the illicit drugs manufacture, whether they are exported, imported or in transit.

Option 4: Increasing the powers of competent authorities and introducing the use of pre-export notifications

EU Member States' competent authorities would have a legal basis not only to stop and seize medicinal products containing ephedrine and pseudo-ephedrine (as in option 3) but also to send pre-export notifications for these products to the country of destination via PEN online (Pre-Export Notification).

Option 5: Subjecting medicinal products containing ephedrine and pseudoephedrine to the same control requirements as ephedrine and pseudoephedrine

Medicinal products containing ephedrine or pseudo-ephedrine would be included in the list of scheduled substances of category 1. They would therefore be subject to the same control requirements to which scheduled substances of category 1, such as ephedrine and pseudoephedrine, are currently submitted: i.e. pre-export notification, export authorisation, license, etc.

Option 6: Banning trade of medicinal products containing ephedrine and pseudoephedrine

In this option, import, export and transit of medicinal products containing ephedrine or pseudoephedrine to, from and through the Union customs territory would no longer be possible.
Before considering a trade ban, other control measures, such as those foreseen in the legislation, should be explored. These measures have been analysed under option 5.
Therefore, option 6 has been discarded without further analysing its impacts.

5. ASSESSMENT OF IMPACTS

This initiative respects the fundamental rights, freedoms and principles contained in the Charter of **Fundamental Rights** of the Union. In particular Article 35 of the Charter guarantees to everyone the right of access to preventive health care and the right to benefit from medical treatment. Empowering competent authorities to act over medicines, as foreseen under options 3, 4 and 5, will not reduce the access to medicines for the public.

No **environmental impact** can be associated with this problem.

It is difficult to determine whether there would be any specific **impact on SMEs or micro-enterprises**, as it was not possible to target in the consultation those marketing specifically medicinal products containing ephedrine or pseudoephedrine. However, SMEs were consulted as part of the pharmaceutical associations. The absence of their replies confirms that they are not much involved in the trade of medicinal products containing ephedrine or pseudoephedrine or are working for the multinational companies that are active in this segment. Therefore, it could be assumed that SMEs would not be affected by this proposal.

International impacts: Diversion of drug precursors is a global problem which requires a global response. If stronger control measures over medicinal products containing ephedrine or pseudoephedrine were taken at EU level, this would match efforts made by other countries in the world, thus contributing to the international objective of strengthening controls over these products.

For policy options 3, 4 and 5, the **administrative burden for the competent authorities** has been quantified using the EU 'Standard Cost model' and on the basis of the data gathered from the stakeholders' consultation. The additional **administrative burden for the industry** could be only partially assessed as no data were provided by the pharmaceutical trade associations and companies that submitted a reply to the online consultation, given that they were all in favour of no legislative action.

Option 1: taking no new legislative action (baseline option)

Effectiveness

The identified weakness of the current legislation with regard to the diversion of medicinal products containing ephedrine and pseudo-ephedrine would remain, allowing traffickers to continue targeting medicinal products to source ephedrine and pseudoephedrine for the illicit manufacture of methamphetamine. Therefore, **this option will not contribute to** fighting the illicit manufacture of methamphetamine by **reducing the supply of ephedrine and pseudoephedrine** contained in medicinal products.

The **free trade flow** of these products for legitimate purposes between the Union and third countries **will be maintained.**

Furthermore, the **EU will continue to be criticised at international level** for remaining "inactive" despite continued calls by the INCB for stepping up the control of its external trade legislation.

Efficiency

This option does not impose any additional administrative burden on European level on either businesses or national competent authorities. As the "business as usual costs" will remain unchanged, the administrative costs will also remain unchanged.

Option 2: Recommending voluntary measures to Member States

Effectiveness

This option will not provide for an EU response to the identified problem. It will however guide those Member States which do not have any control measures in place, to establish some on the basis of the good practice in other Member States which have already taken some and have proven to be effective in reducing the supply of ephedrine and pseudoephedrine for the illicit manufacture of drugs.

The trade flow of these products between the Union and third countries will not be affected.

This option will not comply with the UN Resolutions inviting all Contracting Parties to the 1988 UN Convention to strengthen controls over this type of products.

Efficiency

Whatever measure they may decide to implement, one can assume that it will imply some administrative burden on the national level. The additional administrative burden of any of these national measures is not assessed in the present initiative as it is unclear, which measures Member States might take.

Option 3: Increasing the powers of competent authorities

Effectiveness

This option **will increase the chances to prevent the diversion of these products, thus reducing the supply of ephedrine and pseudoephedrine** for the illicit manufacture of methamphetamine. As this option will establish within the drug precursor legislation a legal

basis for Member States' competent authorities to stop or seize a consignment of medicinal products containing ephedrine and pseudoephedrine, the Member States' competent authorities will no longer have to rely on different national laws where they exist to stop or seize these products.

The trade flow of medicines containing ephedrine or pseudoephedrine will not be hampered.

It will reduce the criticism expressed by the INCB concerning the EU lack of action in imposing control measures over these products.

Efficiency

Controls will thus be performed both at export/import and in transit in all Member States, on the basis of risk analysis. Since this will be part of the normal work of customs, where risk criteria vary according to trends, the additional administrative burden is expected to be minimal. As regards traders, customs controls being part of the normal risk they take in trading goods internationally, the impact is also considered as minimal.

Option 4: Increasing the powers of competent authorities and introducing the use of pre-export notifications

Effectiveness

This option builds on the previous one, thus maintaining all the benefits already outlined. In addition, the use of the PEN-online system will minimise the risk of diversion, as this system ensures a systematic and consistent monitoring of trade in drug precursors globally. Thanks to this tool, this option **will enhance the chances to prevent the diversion of medicinal products containing ephedrine or pseudoephedrine** for the illicit manufacture of methamphetamine.

The use of pre-export notifications (PEN online) for medicinal products by Member States' competent authorities **will be praised by the INCB** who has repeatedly encouraged the Union to do so over the last few years through their annual reports.

Since its creation, **PEN-online has never been recorded as slowing down or hindering trade transactions** as confirmed by the fact that a growing number of countries in the world use it.

Efficiency

The additional administrative burden for competent authorities in relation to the controls they will perform, under the amended Article 26, will remain minimal. The average additional administrative burden for competent authorities for sending one pre-export notification for a category 1 substance amounts at €15. The additional administrative burden will mainly depend on the volume of the licit trade for these products in each Member State. In this respect, it can be assumed that this additional administrative burden is relatively low and that it can be borne by Member State's competent authorities given that several Member States have already been sending them voluntarily over the last three years during the international operational initiatives under Project Prism.

Option 5: Subjecting medicinal products containing ephedrine and pseudoephedrine to the same control requirements as ephedrine and pseudoephedrine

Effectiveness

This option will strengthen considerably controls over medicinal products containing ephedrine or pseudoephedrine, which would be submitted to the same control regime imposed by the drug precursor legislation to the raw substances they contain.

This option will increase the chances to prevent diversion, thus reducing the supply of ephedrine and pseudoephedrine for the illicit manufacture of methamphetamine.

The requirements that would be applicable to these medicinal products would be disproportionate to the objective pursued by the present initiative.

The trade flow of these products between the Union and third countries might be hampered by the increased requirements with which operators will be obliged to comply in order to export or import these products.

Furthermore, this option would imply the amendment of the same article in the Regulation governing intra-EU trade in drug precursors.

This option **will comply with the CND Resolution** inviting amongst others the Union "to apply similar control measures for pharmaceutical preparations containing ephedrine and pseudoephedrine as those for bulk (raw) precursor chemicals"[4].

Efficiency

There are four main administrative requirements: license, import authorisation, export authorisation and pre-export notifications. The additional administrative burden stemming from the requirement of PEN-online has been calculated under option 4.

As regards **licensing**, the current average administrative burden per competent authority for cat 1 substances is €861 per year. Therefore, the current administrative burden per competent authority to issue a licence for these products would be the same as for any other substance of category 1, therefore € 49.

As regards the **import authorisations**, the current average administrative burden per competent authority for cat 1 substances is €1236 per year. The current administrative burden to grant an import authorisation is € 28.

As regards the **export authorisations**, the average administrative burden per competent authority for cat 1 substances is €995 per year. The current administrative burden to grant an export authorisation is € 29.

The administrative burden per company to obtain a licence is € 77 (DG ENTR impact assessment)[5].

[4] Resolution E/CN.7/2011/L.5/Rev.1 on "Strengthening international cooperation and regulatory and institutional frameworks for the control of precursor chemicals used in the illicit manufacture of synthetic drugs".
http://www.unodc.org/documents/commissions/CND-Res-2011to2019/CND54_8e1.pdf

6. COMPARISON OF OPTIONS

The following table indicates the effectiveness and cost efficiency of each option, thus contributing to the analysis of the most preferred one.

Table 1: Comparing the options

Options	Effectiveness			Cost Efficiency		Overall Assessment
	Reducing supply of EPH/PSE contained in medicines by preventing their diversion	Maintaining the free flow of EPH/PSE medicines between the EU and third countries	Compliance with UN Resolutions	Additional administrative burden		
				Per authority	Per industry	
1	-	+	-	€ 0	€ 0	-
2	-/+	+	-	€ 0/+	€ 0/+	-
3	+	+	+	€ 0/+	€ 0/+	++
4	++	+	+	€ 1500*	NA	+++
5	+++	+/-	+	Exports = €9300 Imports = €7700	Licence = €77	++

Even though the baseline scenario does not imply any additional administrative burden, retaining this option should be excluded if the Commission is to respond adequately to the Council's request to address the weaknesses identified in the control system of the drug precursor legislation and to concerns expressed by the international community.

[5] Administrative costs and administrative burdens imposed by amendments of EU drug precursor legislation, Final Report, EIM, October 2011, page 24.

Non-legislative measures, unless adopted across all Member States, would only partially address the identified problem. Moreover, it will not enable competent authorities to stop or seize, be it at export or in transit, medicinal products containing ephedrine or pseudoephedrine due to the lack of a clear legal basis on these specific goods. The measures contemplated under this option would only to a certain extent prevent the diversion of the medicinal products containing ephedrine and pseudoephedrine.

Options 3, 4 and 5 would all provide a clear legal basis for competent authorities to stop and/or seize medicinal products containing ephedrine or pseudoephedrine at export from or in transit through the Union customs territory, when there are reasonable grounds for suspecting that these products are intended for the illicit drugs manufacture. They would all reduce the criticism expressed by the INCB concerning the EU lack of action in imposing control measures over these products and would all increase the chances to prevent the diversion of these products, thus reducing the supply of ephedrine and pseudoephedrine for the illicit manufacture of methamphetamine, though to different degrees.

When comparing these three options providing for legislative amendments, option 3 would generate only minor administrative burden; the same can be expected for option 4, while option 5 would impose the highest administrative burden for both competent authorities and economic operators. Even though option 5 could be considered the most effective insofar as it applies the strictest controls, it would impose too many control requirements that would seem disproportionate to the objective pursued by the present initiative. The added value provided by option 4 if compared to option 3 is that, under this option, the synergy of the two combined measures increases the effectiveness of each individual measure, with a limited additional burden given that the pre-export notification system is up and running and that the number of pre-export notifications that could be seemingly sent per year by Member States' competent authorities is relatively small. Moreover, as pre-export notifications are already compulsory for scheduled substances of category 1, it would seem logical to make them compulsory also for the products containing them, such as medicinal products containing ephedrine or pseudoephedrine.

Option 4 would thus seem the most preferred one: it would provide for an efficient control, would impose only one extra control requirement and it would generate hardly any additional administrative burden.

7. MONITORING AND EVALUATION

The Commission envisages:

- Collection, analysis, and reporting of Member States' annual statistics of seizures and stopped shipments.
- Support the implementation of the amended Regulation through the Drug Precursors Working Group and through updating the existing guidelines, the e-learning tool, FAQ document.
- Implementation of a database currently being developed to facilitate the collection and analysis of statistics.
- Creation of a specific tariff code in the Combined Nomenclature for medicinal products containing ephedrine or pseudoephedrine.

- Organisation of awareness-raising activities involving competent authorities and economic operators.

- Exchange of information, including about trends, with the governments of third countries.

The Commission could undertake an evaluation of its new provisions five years after their adoption, examining the results achieved against the objectives set and assessing any implications of future options. It could then submit a report on the evaluation.