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COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

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) 521 final}
{SWD(2012) 267 final}

TABLE OF CONTENTS

COMMISSION STAFF WORKING DOCUMENT

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1. INTRODUCTION

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 and psychotropic substances. In other words, "there is no production of illicit drugs without drug precursors".

Therefore, controlling drug precursors is a key component in the fight against narcotic drugs. Taking into account the wide legitimate uses of drug precursors, their trade cannot be prohibited. A specific regulatory framework, both at international and at EU level, has been put in place to monitor their legal trade and to identify suspicious transactions, thus preventing their diversion for illicit use. An effective cooperation between the competent authorities and the industry is key to the implementation of this regulatory framework.

These chemicals are rarely produced by criminals that intend to use them for their illicit purposes as their production often requires substantial infrastructure. Criminals tend to either smuggle or divert them from the licit trade by exploiting weaknesses of national control systems to their benefit. The weakness identified in the control system of international trade in drug precursors concerns medicinal products containing ephedrine or pseudoephedrine[1] (drug precursors) exported from or transiting through the Union customs territory which are diverted for the illicit manufacture of methamphetamines[2] in other countries of the world. The EU is criticized internationally for not taking adequate control measures across Member States to tackle this weakness. 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.

By imposing EU control over these medicinal products, we are aiming to make it more difficult, expensive and risky for criminals to source the chemicals they need to manufacture

[1] The term 'medicinal products containing ephedrine or pseudoephedrine' will be used throughout the text, as this is the term used in the EU legislation. However, other terms are used to refer to these products, in particular in case of quotations from international sources, such as: 'pharmaceutical preparations' containing ephedrine or pseudoephedrine or 'medicines' containing ephedrine or pseudoephedrine.

[2] Methamphetamine is a synthetic drug which belongs to the amphetamines-group.

drugs. This proposal should work as a deterrent: it focuses on preventing the diversion of precursors. It does not aim to solve health problems and reduce criminality related to drug abuse; it concentrates on the supply reduction of the chemicals to make drugs and not on the supply of the drugs for the consumers.

The present impact assessment refers to measures to address this specific weakness concerning the trade in drug precursors between the Union and third countries, under Regulation (EC) No 111/2005[3], which is under the responsibility of DG Taxation and Customs Union (DG TAXUD). Another impact assessment, carried out in parallel, concerns intra-EU trade in drug precursors, Regulation (EC) No 273/2004[4], under the responsibility of DG Enterprise and Industry (DG ENTR) and focuses on strengthening controls over acetic anhydride, the main heroin precursors, within the Union.

2. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

The proposal to amend Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors was announced in the 2011 Commission Work Programme and further scheduled in the 2012 Commission Work Programme.

This initiative follows on from the Council *Conclusions on the functioning and implementation of the EU drug precursor's legislation*[5] inviting the Commission "to set a work programme to address the identified weaknesses in the legislation in co-operation with Member States and to propose legislative amendments before the end of 2011 after carefully assessing their potential impacts on Member States' authorities and economic operators".

The Council conclusions were based on the Commission Report to the Council and the European Parliament issued in January 2010[6]. The underlying evaluation to the Commission report had been carried out by the Commission Services, with the assistance of a group of experts from competent national authorities, which had been established for the evaluation purposes. In addition, the Commission had mandated an external contractor, the consultancy RPA to gather further information[7].

2.1. Internal consultations

The preparation of this Impact Assessment was monitored by an Inter-service Steering Group, composed of Directorates General TAXUD, ENTR, HOME, JUST, OLAF and SANCO and from the Legal Service and the Secretariat-General. The Steering Group met on four occasions. Its last meeting was convened on 14 December 2011.

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3 Council Regulation (EC) No 111/2005 of 22.12.2004 laying down the rules for the monitoring of trade between the EU and third countries, OJ L 22 of 26.1.2005, p. 1.

4 Regulation (EC) 273/2004 of the European Parliament and the Council on drug precursors, OJ L 22 of 26.1.2005, p.1.

5 3016th Competitiveness Council meeting Brussels, 25 May 2010 - .

6 Report from the Commission to the Council and the European Parliament pursuant to Article 16 of 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, COM(2009)709 final

7 Ad hoc Study to be used in the evaluation of the Community legislation on drug precursors, Final Report, prepared for the European Commission, RPA, February 2009. Available in pdf format on demand.

2.2. Stakeholder consultation

A stakeholder consultation was held from 30 June to 13 September 2011. This was not a public consultation, given the sensitivity and the peculiarity of the matter at stake. On the one hand, the subject matter, drug precursors, is not widely known and would have most likely entailed responses concerning the overall drug situation, which would have been irrelevant for this exercise. On the other hand, the problem at stake and the envisaged options only affect a very specific aspect of drug precursor control. Only the most concerned stakeholders were therefore consulted. The responses of the stakeholders were treated confidentially; they have not been published on the Commission website to avoid providing sensitive information to traffickers. All the contributions have been taken into consideration for the analysis in this impact assessment.

The consultation consisted of two types of questionnaires[8], one targeted to national authorities and one targeted to the pharmaceutical industry, including small and medium-sized enterprises. The questionnaires were introduced in the Interactive Policy Management (IPM) tool of the Commission. The link to these questionnaires was sent to the specific stakeholders, namely Member States' competent authorities (customs, police and health) and economic operators (9 pan-European[9] pharmaceutical associations representing the major components of the pharmaceutical industry). Two of these pharmaceutical associations with a high proportion of SME member companies were consulted, as it was not possible to target only those SMEs marketing medicinal products containing ephedrine or pseudoephedrine (the databases currently available are devised for commercial purposes and do not allow selecting this kind of information). Small and medium-sized enterprises were also consulted through the Enterprise Europe Network.

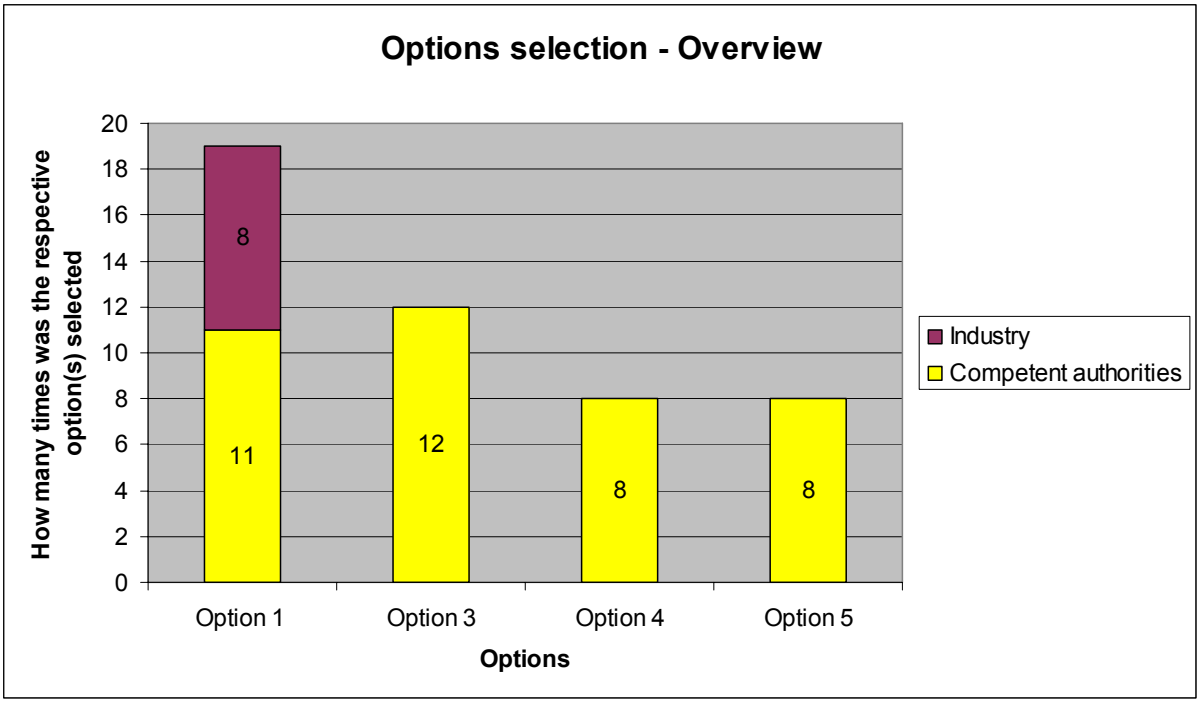
In response to this consultation the Commission received 31 contributions. Of these, 22 were from national authorities (3 of which were partial replies) and 8 from the industry (6 manufacturing companies and 2 pharmaceutical associations). From the absence of replies from SMEs and as confirmed by the industry, SMEs are not much involved in the trade of medicinal products containing ephedrine or pseudoephedrine, or are working for the few multinational firms that are active in this segment.

Chart 1 here below shows that the industry is unanimous in favouring the baseline scenario as they take the stance that this is not an EU-wide problem but rather a regional one. Subsequent consultations with the Association of European Self Medication Industry (AESGP) revealed that options 3 and 4 would not be opposed by industry since the administrative burden on exporting companies would be minimal or even inexistent. However, Member States' competent authorities are equally split among the various options; two thirds plead for an amendment of the legislation, though to different degrees; one third is in favour of no change in the legislation, considering that their drug legislation provides for the possibility for customs and police authorities to stop and seize products, which are likely to be used for the illicit drug manufacture, including medicinal products containing ephedrine or pseudoephedrine. Results concerning option 2 do not appear in this Chart because this option lists a series of measures for which stakeholders were asked only to assess the degree of their effectiveness.

Chart 1. Options selection - Overview

[8] Stakeholders questionnaires are reproduced in Annex 1.

[9] EU Member States and other European countries such as Norway, Switzerland, Croatia.



The Commission maintained regular contacts with the competent authorities of the Member States throughout the review process in the last year and there was an active dialogue to identify the main problems and the possible options to address them, notably:

- through the Drug Precursors Working Group meetings, composed of Member States' representatives and the Commission which meets twice per year;

- through the "Drug Precursors Project Group" created under the Customs 2013 Programme, composed of operational experts from Member States which meets twice per year; and

- at a "Roundtable on medicinal products containing ephedrine and pseudoephedrine", composed of Member States' competent authorities for drug precursors and for medicinal products which was held on 7 December 2009.

The main results of these consultations are summarised in Annex 2.

2.3. Scrutiny by the Commission Impact Assessment Board

The Impact Assessment Board of the European Commission assessed a draft version of the present impact assessment and issued its opinion on 29 February 2012. The Impact Assessment Board made several recommendations and, in the light of the latter, the final impact assessment report:

- presents the scope of the proposal more clearly;

- indicates the volume of licit trade of medicinal products containing ephedrine and pseudoephedrine at European and at global level;

- explains how these products are diverted for the illicit manufacture of methamphetamine;

- gives an overview of the drug legislation in the Member States and of the powers of their customs and police authorities;

- considers a sixth option which consists in a trade ban of these products;

- strengthens the analysis of impacts through better emphasizing the cost-efficiency and effectiveness criteria; and

- provides an overall evaluation review exercise, as well as specific progress indicators.

3. POLICY CONTEXT

3.1. International context

The United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances contains in its Article 12 specific reference to measures to prevent diversion of drug precursor chemicals for use in the illicit manufacture of narcotic drugs and psychotropic substances. Tables I and II of the 1998 Convention contains the list of 23 drug precursors (so-called "scheduled substances") which are controlled by the Convention because they are most frequently used in the production of illicit drugs.

The EU is a Contracting Party of Article 12 of the 1988 UN Convention, which has 185 Parties including all major chemical producing countries. The EU has implemented its obligations through legislation and voluntary measures applied by the public and private sectors.

The United Nations' International Narcotics Control Board (INCB) is an independent control body which closely monitors the implementation of the United Nations drug conventions. It publishes annual technical reports containing diversion statistics and their analysis as well as recommendations to the countries concerned.

According to the 2009 INCB report, 70% of all identified instances of suspicious shipments or diversions of methamphetamine precursors currently involve ephedrine or pseudoephedrine in tablet form.[10] This trend was further confirmed by the results of the activities under Project PRISM[11] with an emphasis on pharmaceutical preparations containing ephedrine or pseudoephedrine[12], as outlined in the 2010 INCB report[13]. In particular, of 35 cases of seizures of ephedrine and pseudoephedrine during Operation Crystal Flow, 40 cases during Operation Ice Block and 139 cases during Operation Pila, 11%, 27.5% and 67% respectively were in the form of medicinal products. Some countries have therefore strengthened measures to control these products: e.g. Malaysia and Thailand request to receive pre-export notifications for transactions involving these products and require an import/export licence for all import/export of these products in the same way as the substances they contain. Other countries, such as Mexico, several Central American countries, and Colombia entirely prohibit imports of these products. The United States also control medicinal products containing ephedrine or pseudoephedrine as List I chemicals under the Controlled Substances Act. This means that these products are submitted to the same control regime imposed to the

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10 INCB 2009 Annual Report on Precursors: p.xii
http://www.incb.org/pdf/precursors-report/2009/English/Precursors_Report_09_english.pdf

11 Project PRISM (**P**recursors **R**equired **I**n **S**ynthetic drugs **M**anufacturing) is a United Nations/INCB-led project to address diversion and trafficking of amphetamine-type stimulants (AES) precursors.

12 This is the term internationally used to refer to medicinal products or medicines containing these two drug precursors.

13 INCB 2010 Annual Report on Precursors: p. 6
http://www.incb.org/pdf/precursors-report/2010/en/PrecursorsReport2010_E_V10579291.pdf

raw substances they contain, which are List I chemicals. They are controlled regardless of their form – bulk substances (raw material) or tablets.

Since 2006, the Commission on Narcotic Drugs[14] (CND), the central drug policymaking body within the United Nations, adopted various Resolutions inviting all Contracting Parties to strengthen controls over this type of products (the latest at the 2011 CND meeting[15]), in particular to adopt regulatory framework to control these products containing precursors and to encourage the use of the pre-export notification system for these products so as to favour the rapid identification of new patterns of diversion. CND Resolutions shape global drug control policy and direct the work of the UN Office of Drugs and Crime (UNODC) and of the INCB on these matters.

3.2. EU context

Since the early nineties the EU has put in place legislation to ensure that diversion of drug precursors is prevented through control and monitoring of their legitimate trade. The existing legislation aims at striking a balance between necessary actions to prevent diversion of drug precursors and allowing their legitimate trade without creating unnecessary administrative burdens.

The EU legislation on drug precursors, just like the 1988 United Nations Convention, covers the same 23 drug precursors which are divided in three categories according to their sensitivity:

- Category 1 covers the most sensitive substances (12 substances);

- Category 2 covers less sensitive substances and "pre-precursors"[16] (5 substances);

- Category 3 covers bulk chemicals that can have different types of uses in the manufacturing process, such as feedstock, but also solvents and impurities remover (6 substances).

The extent of control of operators and of trade transactions depends on the Category concerned: the strictest control applies to category 1 substances, while the least control is imposed on substances of category 3. A summary table comprising the obligations is attached in Annex 3.

Furthermore, the legislation builds upon the key principle of partnership between authorities and operators in identifying diversion attempts; a voluntary monitoring system is in operation for non-controlled substances, providing flexibility[17] for rapidly changing diversion patterns.

The control of drug precursors is part of the EU Drugs Strategy[18] and the EU Drugs Action Plan (2009-2012)[19], which sets out the objective to reduce the diversion and trafficking in/via the EU of drug precursors used for the illicit manufacture of drugs.

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14 Established in 1946, the Commission on Narcotic Drugs reviews and analyses the global drug control situation, considering the interrelated issues of prevention of drug abuse, rehabilitation of drug users and supply and trafficking in illicit drugs. It takes action through resolutions and decisions.

15 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

16 Substances which are used to produce another precursor.

17 Non-scheduled substances can be added or withdrawn form the voluntary monitoring list upon request of one Member State and by decision of the Drug Precursors Working Group.

The responsibility for drug precursors in the Commission is shared between DG TAXUD and DG ENTR. DG TAXUD is in charge of Council Regulation (EC) No 111/2005 governing the trade in drug precursors between the EU and third countries, while DG ENTR is in charge of Regulation (EC) 273/2004 of the European Parliament and the Council relating to the trade in drug precursors within the EU.

As mentioned under point 2 above, the European Commission's Report COM(2009)709 assessed the functioning of the existing EU legislation on drug precursors and, while concluding that the system overall functions well, it also identified some weaknesses in the existing control system of trade in drug precursors both within the Union and between the Union and third countries.

As announced in the Introduction, two impact assessments on the European drug precursor legislations are carried out in parallel by DG TAXUD in respect of extra-EU trade and by DG ENTR in respect of intra-EU trade.

Even though both initiatives concern the drug precursors' legislation, they tackle two issues which are not interlinked. This is the reason why, despite the common background, two separate initiatives have been put forward. The two DGs have nevertheless ensured coordination all through the procedure of preparation and writing of the respective impact assessments.

4. PROBLEM DEFINITION

4.1. Scope of the problem

Ephedrine and pseudoephedrine are chemical substances used for the manufacture of cold or allergy medicines as they are effective nasal decongestant. These two substances are also the key precursors for the manufacture of methamphetamines. While the raw substances, ephedrine and pseudoephedrine, are internationally controlled according to the 1988 UN Convention, medicinal products containing ephedrine or pseudoephedrine are not controlled as they are excluded from the scope of the UN Convention. Based on the 1988 UN Convention, the EU legislation also provides for the control of ephedrine and pseudoephedrine but it does not provide for the control of medicinal products containing ephedrine or pseudoephedrine for human use[20]. These products are regulated in accordance with Directive 2001/83/EC on the Community code relating to medicinal products for human use[21] and belong to the category of over-the-counter medicines[22] or non-prescription drugs.

The focus of this impact assessment is not on over-the-counter-medicines as a category but only and exclusively on the medicines for human use containing ephedrine or pseudoephedrine (drug precursors).

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18 EU Drugs Strategy 2005-2012, endorsed by the European Council of November 2004 (15074/04 CORDROGUE 77 SAN 187 ENFOPOL 187 RELEX 564).

19 EU Drug Action Plan for 2009-2012 (2008/C 326/09).

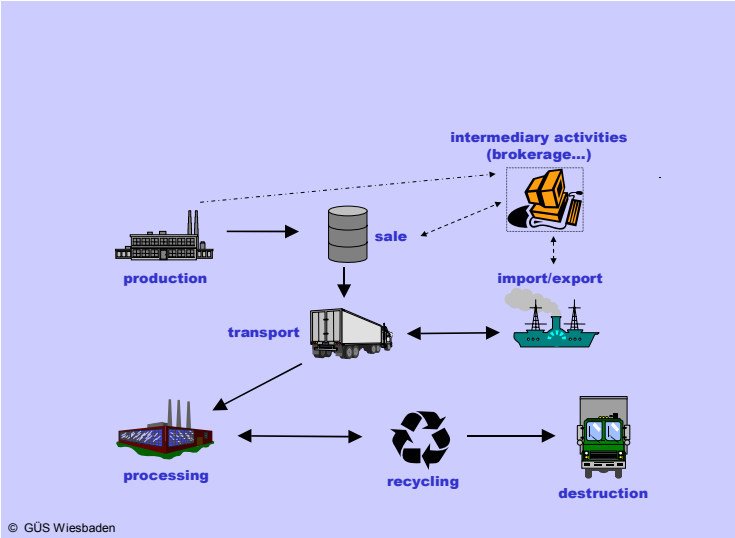
20 Medicinal products containing ephedrine or pseudoephedrine for veterinary use are instead not excluded in the EU drug precursor legislation.

21 OJ L 311 of 28.11.2001, as amended.

22 Over-the-counter or OCT drugs are medicines that may be sold directly to a consumer without a prescription from a healthcare professional, as compared to prescription drugs, which may be sold only to consumers possessing a valid prescription.

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 methamphetamines. There is a growing international concern about increased diversion of ephedrine and pseudoephedrine when contained in medicinal products - this is one of the findings of the ad hoc study for the evaluation of Community legislation on drug precursors of 2009.

Diversion of precursors from licit trade can occur at any stage of handling, as illustrated in the chart here below:



Traffickers have several modus operandi to divert chemicals. The list here below is not exhaustive but gives an overview of the main patterns.

Criminals often try to cover their true identity, for instance, by using false names and addresses; by using front-men, front companies or corrupt companies; by misusing bona-fide names of well-known international companies.

They often use criminal means to obtain chemicals, for instance, bribery or coercion of legal companies, blackmailing employees; theft of chemicals; falsification of documents (e.g. use of false licences).

They often disguise and blur the destination and the consignee of a transaction, for instance, by offering cash-payment, by using unconventional means of money transfer or transport; by destroying documents relating to the transaction; by picking up the chemicals themselves.

They often disguise the nature of the substance intended to be diverted, for instance, by making use of or asking the supplier to put wrong, falsified, modified or no labels; by making use of or asking the supplier to use generic names for the substance (e.g. “solvent”, "thinner").

According to the 2010 INCB Report, the EU is still being used as a transhipment[23] point, with Germany, the Netherlands, Spain and the United Kingdom of Great Britain and Northern Ireland having been associated with shipments from South and South-East Asia destined for

[23] The terms 'transhipment' and 'transit' are used interchangeably in the INCB Reports, as the act of shipping goods to an intermediate destination prior to reaching their ultimate end-use.

Belize, Guatemala and Mexico[24], where large scale illicit methamphetamine manufacture takes place. The 2009 INCB report already stated that the route by which tableted preparations were shipped to destinations in Central America passed through countries of the European Union. In October 2008, French authorities seized three consignments of pseudoephedrine preparations, the largest of which involved 11 million tablets transiting from the Syrian Arab Republic to Honduras. The other two shipments were destined for Guatemala, one originating in India and the other in Vietnam[25].

The fact that medicinal products for human use containing ephedrine or pseudoephedrine are excluded from the provisions of Regulation (EC) 111/2005 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, as proven by the results of the international operational initiatives launched under Project PRISM[26]. Some Member States customs authorities have however been using provisions of national anti-drugs laws or the customs code to stop or seize such goods, with more or less success. Drug traffickers therefore use the loophole in the drug precursor legislation to source this type of products.

Without a specific legal basis in the drug precursor legislation, several Member States consider that customs control over medicinal products containing ephedrine or pseudoephedrine when exported or in transit cannot be performed with a view to seizing or stopping these products. For example, in 2008 eight airfreight consignments of medicinal products for human use containing ephedrine were exported from the EU to Mexico and another sea container was exported to Belize. These transactions presented a combination of risks indicators that would have urged the competent authorities to prevent the export of the products, had they had the legal ground to perform them. This would have prevented these products from being diverted to the illicit manufacture of methamphetamine in Mexico, as it was established by the investigation carried out a posteriori.

4.2. Scale of the problem (methamphetamine and its precursors)

In Europe[27] illicit methamphetamine production is concentrated in the Czech Republic and in Slovakia. In recent years, methamphetamine has also appeared on the drug market in other countries in the north of Europe (Norway, Sweden, Latvia and Finland), where it appears to have partially replaced amphetamine, the two substances being virtually indistinguishable to users of the drugs. In 2009 almost 7400 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, including Austria, Lithuania, Netherlands, Poland, Portugal and Belarus. This is an indication that methamphetamine markets may be expanding in Europe.

At global level, in 2009, North America accounted for 44% of global seizures of methamphetamine, due to the continued high level of seizures in the United States (7.5 mt[28],

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24 INCB 2010 Annual Report on Precursors: Point 41, p. 7 http://www.incb.org/pdf/precursors-report/2010/en/PrecursorsReport2010_E_V10579291.pdf

25 INCB 2009 Annual Report on Precursors: Point 55, p. 9 http://www.incb.org/pdf/precursors-report/2009/English/Precursors_Report_09_english.pdf

26 See section 3.1 paragraph 4.

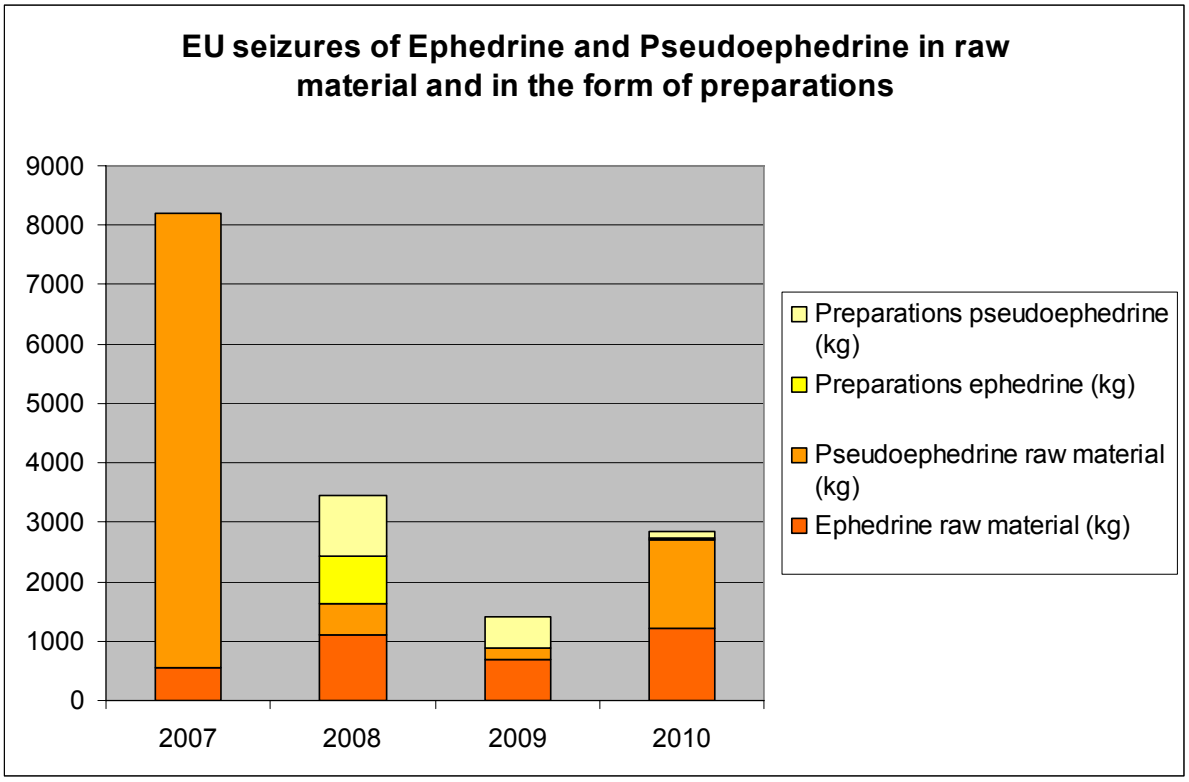
27 EMCDDA 2011 Annual report on the state of the drugs problem in Europe (data of 2009), pages 14-15.

28 Mt = metric tons. 1 mt = 1000 kg

compared with 7.4 mt in 2008) as well as to a sharp increase in methamphetamines seizures in Mexico which reached a comparable level (6.1 mt, up from 341 kg in 2008). The Asia-Pacific region (Cambodia, Laos, Myanmar, Thailand, Viet Nam and China) continued to be affected by manufacture, trafficking and consumption of methamphetamine on a large scale. In 2009, seizures in East and South-East Asia rose by more than one third, from 11.6 mt in 2008 to 15.8 mt. There are signs that methamphetamine is reaching the region from Africa and the Islamic Republic of Iran. West Africa is also emerging as a new source of methamphetamine for the illicit Asian markets, with couriers transiting Europe, West Asia or East Africa[29].

Ephedrine and pseudoephedrine are the main precursors for methamphetamine. From 2007 until 2010, seizures of methamphetamine precursors contained in medicinal products by EU Member States' competent authorities at the borders have fluctuated considerably (see Chart 2 below): while in 2007 hardly any preparations were recorded out of the overall quantities seized (0.3 mt out of 8 mt), in 2008 and 2009 the amount of preparations 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). In 2010 this amount decreased considerably (0.1 mt out of 2.9 mt) even though increased quantities of ephedrine and pseudoephedrine (raw material) were seized compared to the previous years. Even though this amount decreased considerably in 2010, many Member States and the International Narcotics Control Board (INCB) are concerned about the absence of a control mechanism for the medicinal products containing ephedrine and pseudoephedrine.

Chart 2: EU seizures of ephedrine and pseudoephedrine in raw material and in the form of preparations



Source: DG TAXUD on the basis of the figures from the UNODC World Drug Report 2011.

[29] UNODC World Drug Report 2011, pages 156, 160 and 166.

Global seizures of methamphetamine precursors have fluctuated significantly. From 2007 until 2009, the following amounts were seized: 53 mt of these precursors of which 10% were in the form of pharmaceutical preparations; 49 mt of which 30% in the form of preparations; 53 mt of which 67% were preparations; and 89 mt of which 75% were in the form of pharmaceutical preparations[30].

After the continued increase of seizures of pharmaceutical preparations from 2007 to 2009, as a result of strengthened controls of pharmaceutical preparations containing ephedrine and pseudoephedrine in several countries, particularly in Mexico and countries in Central America, the total amount of preparations seized worldwide has decreased in 2010. The amount of pseudoephedrine in the form of pharmaceutical preparations accounted in 2009 for 38% and in 2010 for 25% of total pseudoephedrine seized worldwide. In south-East Asia pharmaceutical preparations are increasingly used for the manufacture of methamphetamine. A recent case shows that large quantities of cold medicines containing pseudoephedrine have gone missing from hospitals in Thailand. The drugs are thought to have been sent across the border to Myanmar and Laos where they are used in the production of methamphetamines which are then smuggled back into Thailand for sale. From 2008 to the present, Thai authorities have seized more than 48 million cold pills containing pseudoephedrine. The pills were stolen from the public health system (hospitals and drug stores). It is believed there is still a large amount of stolen pills that have not been recovered[31]. Oceania remains a common destination for smuggled ephedrine and pseudoephedrine in both forms. Together, Australia and New Zealand accounted for 1.7 tons, mostly seized in the form of pharmaceutical preparations. Diversion of pharmaceutical preparations containing pseudoephedrine from pharmacies remains the primary source of precursors used in the high number of small-scale illicit methamphetamine laboratories in the United States.

It appears that even though seizures are decreasing in the EU, they are instead increasing globally. 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. Another indicator could be the amount of precursors diverted in comparison with the volume of the licit trade for a given precursor and/or of medicinal products containing ephedrine or pseudoephedrine. For any of the precursors under international and European control, it is possible to determine the volume of trade as each precursor has a specific tariff code in the customs nomenclature allowing to target that specific substance. For the purpose of this initiative, it would be useful to determine the volume of trade of medicinal products containing ephedrine or pseudoephedrine in order to determine the percentage which is diverted for illicit uses. As there are no specific Harmonised System codes[32] (yet) for medicinal products containing ephedrine and pseudoephedrine, Governments are not in a position to track their trade systematically.

The only indicator that can currently be used to determine the licit trade of these products is the information annually reported by the Governments on the Form D[33]. Unlike the mandatory reporting on seizures and illicit trafficking of precursors, Form D reporting on licit trade is voluntary, pursuant to resolution 1995/20 of the Economic and Social Council. Therefore, the licit trade data reported on the Form D can be partial and have to be interpreted with caution.

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30 Source: intelligence data from INCB.

31 Source: The Bangkok Post newspaper, published on 26 March 2012.

32 Further details under section 6.1.

33 Form D is a specific form used by the INCB to request Governments to provide annual information on substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances, from their licit trade to their seizures, and methods of diversion.

Table: Licit trade based on the 2010 Form D data:

2010 Form D data	IMPORTS (kg)		EXPORTS (kg)	
	EU	**Global**	**EU**	**Global**
Ephedrine raw material	26299	99954	18296	106719
Ephedrine preparations	3114	3986	2439	5704
Pseudoephedrine raw material	39899	898251	239288	838708
Pseudoephedrine preparations	753	44546	1003	50938

According to the 2010 Form D data reported to the International Narcotics Control Commission, the EU imported 3114 kg of ephedrine preparations while the global figure was close to 4000 kg. The EU figure accounts for about 78% of the global imports of ephedrine preparations.

As regards the exports of ephedrine preparations in 2010, EU exported 2439 kg which accounts for about 43% of the global exports reported.

In 2010, EU imports and exports of pseudoephedrine preparations amount to about 2% of the global imports and exports reported.

An attempt could be made to determine the existing demand of ephedrine and pseudoephedrine for the purpose of methamphetamine production by making a back-calculation from the use of methamphetamine in specific high-prevalence countries. However, this would be misleading as methamphetamine can also be produced with other drug precursors such as BMK or phenyl acetic acid.

4.3. Underlying drivers of the problem

The drivers can be summarised as follows:

- control measures over ephedrine and pseudoephedrine (the substances) have been strengthened worldwide. Some countries of the world[34] have gone to the extent to prohibit the imports of these substances.

- therefore, traffickers need to look for alternative sources of ephedrine and pseudoephedrine to manufacture methamphetamines; they are targeting medicinal products containing these substances which are not subject to strict control measures; and

[34] Mexico, Colombia and several Central American countries. See Annex 4 for further details.

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

4.4. Foreseen evolution of the problem

It is difficult to foresee the evolution of future diversion trends, as traffickers rapidly adapt to pressure from regulatory and law enforcement authorities by changing their modus operandi using alternative trafficking routes and manufacturing methods in order to circumvent legislative controls.

It is likely that strengthening controls over export and/or transit of medicinal products containing ephedrine and pseudoephedrine in the EU legislation will result in traffickers targeting other parts of the world where there are no or weaker control measures on these products and/or sourcing alternative substances which can be used to manufacture methamphetamines. However, in case of no action at the Union's level, it is likely that traffickers will keep on targeting the EU for diverting these products when exported or in transit.

Moreover, the EU will continue to be pressured by the UN to take action as it is the case since 2006 when the issue first arose.

4.5. Who is affected by the identified problem?

The identified problem may affect:

- third countries, where methamphetamines 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;

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

4.6. EU right to act

The European Union has exclusive competence in the area of common commercial policy, as provided for in paragraph 1 of Article 3 of the Treaty on the Functioning of the European Union (TFEU). Article 207 of the TFEU defines common commercial policy and trade in drug precursors falls within this definition.

In some of its policy options this initiative suggests regulating medicinal products containing ephedrine and pseudo-ephedrine which are already regulated by Directive 2001/83/EC. The preamble to Directive 2001/83/EC states that the essential aim of any rules governing the production, distribution and use of medicinal products, must be to safeguard public health and that this must be attained without hindering the development of the pharmaceutical industry or trade in medicinal products within the Community. However, the directive does recognise that special measures may be required to control the distribution of narcotic and psychotropic substances within the territory of Member States. In any case the objective pursued in this

initiative differs, without contradicting from those pursued by the Directive. The control mechanisms foreseen in Directive 2001/83/EC and in Regulation (EC) 111/2005 are different as they pursue different goals. It is important, however, that any amendments do not present unnecessary obstacles to patients' legitimate access to authorized medicinal products.

EU Member States currently try to curtail traffickers' attempts to divert medicinal products containing ephedrine or pseudoephedrine through different types of national measures, such as strengthening control measures for these products by amending the national legislation in areas of national competence, such as for drugs or medicines. This leads to potential distortions, resulting from differing legal requirements for EU economic operators. Whether such measures have had an impact on the export of medicinal products containing ephedrine or pseudoephedrine potentially diverted to methamphetamine production in third countries is not documented. Other national measures, such as the seizure of medicinal products containing ephedrine or pseudoephedrine by customs in some Member States on the basis of national anti-drugs laws or the customs code also result in a difference of control approaches and actions at the EU external borders. It is not always possible to qualify the offence and apply the penalties foreseen for activities related to drug trafficking, in particular when goods are seized under the customs code.

5. OBJECTIVES[35]

5.1. General policy objectives

In line with the EU Drug Strategy 2005-2012, the general objective of this initiative is to contribute to the world-wide combat against the illicit manufacture of drugs.

5.2. Specific policy objectives

To fight the illicit manufacture of methamphetamines, by controlling the supply of ephedrine/pseudoephedrine contained in medicinal products that are traded between the Union and third countries by 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.

5.3. Operational objectives

In order to contribute to the fight against the illicit manufacture of methamphetamines, the operational objective is to achieve and maintain a downward trend of diversion attempts of medicinal products containing ephedrine or pseudoephedrine from the licit trade.

5.4. Consistency with other policies and objectives

The objective of achieving an effective prevention of diversion of drug precursors to the production of illicit drugs is ultimately aimed at reducing the supply of illegal drugs. It is thus

[35] See table in Annex 5.

consistent with the drug policy outlined in the EU Drugs Strategy 2005-2012, providing for action to reduce the supply of precursors, and, thereby, decrease the production of drugs.

In some of its policy options this initiative suggests regulating the external trade in medicinal products containing ephedrine and pseudo-ephedrine which are already regulated by Directive 2001/83/EC. However, the objective pursued by the Directive is to safeguard public health by controlling medicinal products in order to ensure their quality, safety and efficacy. Therefore, the control mechanisms foreseen in Directive 2001/83/EC and in Regulation (EC) 111/2005 are different as they pursue different goals.

The medicinal products legislation has recently been amended by Directive 2011/62/EU which relates to the prevention of the entry into the legal supply chain of falsified medicinal products. The Directive addresses *inter alia* the distribution chain for medicines within the EU, importation of active pharmaceutical ingredients, 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 new 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.

6. POLICY OPTIONS

Five policy options have been identified. The baseline scenario is outlined as option 1 to map out how the situation could be expected to develop if no remedial action was taken. Option 2 considers contributing to improve the situation through voluntary measures by Member States, while options 3, 4 and 5 consider resolving it through compulsory control measures. The last three options have been built as a crescendo depending on the number and strength of the control measures suggested. These policy options were presented to stakeholders for comment. A further policy option has been considered after this consultation and has been discarded for the reasons explained below. Therefore, no further analysis of its impact has been carried out.

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

In this option, no measure will be proposed. In the current legislation drug precursors, such as ephedrine and pseudoephedrine are subject to specific control requirements, with regard to external trade, while medicinal products containing these precursors are not. Therefore, under the current drug precursor legislation, Member States' authorities cannot stop or seize these products when they enter or leave the Union customs territory, even though it is likely that they would be misused for the illicit manufacture of methamphetamines.

This has been proven by the results achieved during the international activities organised under Project PRISM since 2007 which focused on trade in ephedrine and pseudoephedrine, including medicinal products containing these two substances[36].

Member States who are particularly affected by the diversion of these products on their market have taken some measures to control the distribution of these products. For instance,

[36] See section 3.1 paragraph 4.

Poland has recently restricted purchases of over-the-counter medicines containing pseudoephedrine to a total of 720 mg of pseudoephedrine salts in one or more medicinal products per transaction by amending their Drug Prevention Act. This measure will not be an impediment to purchasing medicinal products for the purpose of treating infections of the respiratory tract. It will, however, prevent bulk purchasing of medicinal products by some consumers for non-medical purposes. Another example is given by the Czech Republic where pharmacies must enter all ephedrine and pseudoephedrine sales in a central register to verify that the product has not been sold to that particular person in the same week and purchase of these products over the internet by mail order has been prohibited.

As mentioned above, some Member States customs seize medicinal products containing ephedrine or pseudoephedrine on the basis of national anti-drugs laws or the customs code. This results in a difference of control approaches and actions at the EU external borders. It is also not always possible to qualify the offence and apply the penalties foreseen for activities related to drug trafficking, in particular when goods are seized under the customs code because they have been misclassified[37].

While drug precursor control is an area of Union competence, drug is instead an area of shared competence. This implies that each Member State develops its own drug legislation, even if they all pursue the objectives enshrined in the five-year EU Drug Strategy. From the overview given in Annex 6, it appears that in one third of Member States the drug legislation allows customs authorities to stop and seize medicinal products containing ephedrine or pseudoephedrine when it can be proven that they might be misused for the illicit drug manufacture. The customs authorities of two thirds of Member States are not empowered for this by their respective drug legislation.

The INCB has recently requested the World Customs Organisation (WCO) to create in the Harmonised System (HS) a specific tariff code for medicinal products containing respectively ephedrine, pseudoephedrine and nor-ephedrine in order to better monitor their licit trade. For the time being, these products fall within the category of medicinal products containing alkaloids; therefore, they cannot be targeted for specific purposes. Even though the decision to create these new tariff codes will be taken in the near future, the new codes will only be applicable as from 1 January 2017. It is consolidated practice that the Harmonised System is amended every 5 to 6 years. The latest amendment entered into force in 2012 and was the fourth one since 1996. Meantime, the European Commission has undertaken to create new tariff codes in the EU Combined Nomenclature to identify medicinal products containing respectively ephedrine, pseudoephedrine and nor-ephedrine, through the relevant Committee in accordance with the Rules of Procedure of the Customs Code Committee[38]. Once these codes are in place, companies exporting and importing these medicines will have to indicate them in the customs declaration. This will allow determining the volume of trade (import and exports) of these specific products. These codes will be available as of January 2013 through the amendment of Commission Regulation (EU) No 1006/2011 of 27 September 2011 amending Annex 1 to Council Regulation (EEC) No 2658/87 on the Tariff and Statistical Nomenclature and on the Common Customs Tariff. This Annex is updated annually in order to take into account any changes that have been agreed at international level, either at the World Customs Organisation with regard to the nomenclature at HS level, or within the framework of the World Trade Organisation with regard to conventional rates of duty.

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37 The tariff classification indicated in the customs declaration does not correspond to the product.

38 Customs Code Committee – Tariff and Statistical Nomenclature section (Agricultural/Chemical sector).

Currently trends and diversion patterns of medicinal products containing ephedrine or pseudoephedrine can be determined thanks to the regular exchange of information between the EU and third countries in the framework of their bilateral agreements on drug precursors[39].

The stakeholders' consultation showed that this option is favoured by those Member States who consider themselves as not directly affected by the diversion of medicinal products containing ephedrine or pseudoephedrine, either because they have no seizures or because they have drug legislation in force which already allow them to stop and seize these products.

6.2. Option 2: Recommending voluntary measures to Member States

In this option, the Commission would make a Recommendation to encourage Member States' authorities to exchange best practices for the control of medicinal products containing ephedrine and pseudo-ephedrine, following the existing examples (see option 6.1).

Measures to be considered under this option are the following:

- restricting the availability of purchases of over-the-counter medicines containing ephedrine/pseudo-ephedrine through compulsory prescription;

- raising awareness of pharmacies concerning the risk of diversion of medicinal products containing ephedrine and pseudo-ephedrine through a national campaign;

- enhancing cooperation between competent authorities and pharmaceutical companies: these companies are well placed to notify the authorities of any suspicious order for export of medicinal products, thus allowing an early detection of possible misuse of the products;

- increasing cooperation among EU Member States authorities and with the European Commission, on a voluntary basis, by exchanging data on licit exports from the EU and products that have been found by customs as smuggled, and inspections on companies established in several Member States;

This list is not exhaustive. Other measures could be developed in cooperation with Member States in the future, drawing from the "Information Package on the control of precursors- for use by competent regulatory and tax enforcement authorities only"[40].

A Commission Recommendation would thus list a number of measures from which each Member State can "pick and choose" as they deem it appropriate. These measures are not in themselves a solution to the diversion of medicinal products being exported from or transiting through the EU. However, if followed in all Member States, they may have a deterrent effect of pushing traffickers seeking methamphetamine precursors out of the EU borders. They could also support the non-EU countries in their identification of suspicious transactions involving the EU customs territory.

The same Member States, who consider themselves as not directly affected by the diversion of medicinal products containing ephedrine or pseudoephedrine, are also in favour of this option as they consider that it is not an EU-wide issue and should therefore be left to their

[39] The EU currently has concluded ten agreements on drug precursors, namely with Turkey, the United States, Mexico, Chile, Bolivia, Colombia, Ecuador, Peru, Venezuela and China.

[40] E/INCB/2011/WP.5 – this document is confidential.

discretion whether they deem necessary to implement certain control measures on their market.

6.3. Option 3: Increasing the powers of competent authorities

In this option, powers would be granted to EU competent authorities to stop transactions involving not only scheduled substances but also medicinal products containing ephedrine and pseudoephedrine, when there are reasonable grounds for suspecting that these products are intended for the illicit drugs manufacture, whether they are exported, imported or in transit.

This can be achieved by amending article 26 §1 so that it applies also to medicinal products containing ephedrine or pseudo-ephedrine and thereby derogating from the exclusion of medicinal products for human use in Article 2 (a)[41].

Those Member States who consider themselves directly concerned by the diversion of these medicinal products (either because they have seizures or because they have no other legislation in place allowing their authorities to stop and seize these products) favour this option. Most member States are also in favour of the following option (option 4) as they consider the use of pre-export notification has an added value to the overall control system.

6.4. Option 4: Increasing the powers of competent authorities (Option 3) and introducing pre-export notifications

In this option, competent authorities would have power not only to stop and seize medicinal products containing ephedrine and pseudo-ephedrine (as in option 3) but would also send pre-export notifications for these products to the country of destination via PEN online (Pre-Export Notification).

Currently, Member States' competent authorities have the obligation under Article 11[42] to send pre-export notifications for all exports of category 1 substances, as well as for exports of certain category 2 substances, to the competent authorities of the country of destination. This system enables these authorities to verify the licit purposes of the transaction and to refuse, in case of suspicion, to import the consignment within a period of 15 working days. In case of no reply, it is assumed that the consignment is licit and can be exported. Moreover, simplified pre-export notification procedures can be applied by competent authorities when they believe that this will not result in any risk of diversion.

PEN-online, developed by the International Narcotic Control Board in 2006, is an internet-based, automated system allowing real-time exchange of information concerning legitimate trade in chemicals between trading countries.

This system is currently used for import and export of scheduled substances. However, it could potentially be used to inform the country of transit, when known, about a future transaction but this feature of the system is currently not exploited.

This option can be achieved by amending Article 26 (as in option 3) and Article 11 of Regulation (EC) 111/2005 so that it applies also to medicinal products containing ephedrine

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41 This Article includes the definitions of the main terms used in the Regulation. The entire Article 2 is reproduced in Annex 7.

42 The entire Article 11 is reproduced in 7.

or pseudo-ephedrine. Under this option, for an intended export of medicinal products, the EU competent authorities will be filling in the pre-export notification with the information provided by the exporting company in the customs declaration, which is the document which must be presented to customs at import or export. The pre-export notification will be sent through PEN-online to the authorities of the importing country, as declared by the exporting company. Once the authorities of the importing country have confirmed that the transaction is licit, the exportation can take place.

6.5. Option 5: Subjecting medicinal products containing ephedrine or pseudoephedrine are subject to the same control requirements as ephedrine and pseudoephedrine

In this option, medicinal products containing ephedrine or pseudoephedrine would be subject to the same control requirements to which scheduled substances of category 1, such as ephedrine and pseudoephedrine, are currently submitted.

Trading in these substances entails a series of obligations for the operators: they must notify suspicious transactions or orders to the competent authorities; they must appoint a responsible officer who ensures compliance with the legislation; they must obtain a licence; they must also obtain an export or import authorisation; they must document and label all transactions and keep records for 3 years and report annually to the competent authorities on exports, imports and intermediary activities[43]. The obligations on the operators imply a series of tasks to be performed by the competent authorities, i.e. to grant an export and/or import authorisation; they must issue a licence. The competent authorities will also have to check the legitimacy of an order before sending a pre-export notification to the country of destination.

Medicinal products containing ephedrine and pseudoephedrine would therefore be subject to the control mechanism and obligations foreseen for scheduled substances of category 1 by:

- amending Article 2 (a) of Regulation (EC) 111/2005 through specifying that the exclusion of medicinal products defined by Directive 2001/83 does not apply to medicinal products containing ephedrine or pseudoephedrine; and

- amending the Annex to this Regulation by including medicinal products containing ephedrine or pseudoephedrine in the list of category 1 substances.

The competent authorities of a few Member States would like to see these products being controlled as the substances they contain, even though they are aware of the administrative burden that would be imposed.

6.6. 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 will no longer be possible.

This would go beyond the measures in force under the current drug precursor control system, where no substance has been banned so far. The existing legislation allows for monitoring the licit trade in drug precursors and preventing diversion by targeted interventions by public

[43] More details on how the control system works can be found in the "Guidelines for operators" (page 8) - Annex 3.

authorities, such as the seizure of substances that are suspected of, or the result of a diversion for producing illicit narcotic drugs. Additionally, to be effective, a ban on international trade in the EU would have to be complemented by a ban on production and commercialisation within the EU.

The proportionality of a ban needs to be assessed against the consequences on legitimate producers and users of the medicinal products concerned, including the possibilities of substitution of the banned products.

Ephedrine and above all pseudoephedrine are nasal decongestants contained in many cough and cold medicines sold over-the-counter in most EU Member States. In the EU, non-prescription medicines represent 50% of pharmaceutical products in volume, cough products representing one of the main categories. The impact of a ban on these products on the market, i.e. for the pharmaceutical industry and subsequently the patients, would be very significant. It would be necessary to find an appropriate substitute chemical for the production of these widely and commonly used medicinal products, which would require clinical tests that could last several years. Phenylephrine has been marketed as a substitute for pseudoephedrine in the production of cold medicines in those Central America countries which have gone to the extent to prohibit both the substances (ephedrine and pseudoephedrine) and the medicinal products containing them. However, there are claims that oral phenylephrine may be no more effective as a decongestant than a placebo[44].

Before considering a trade ban, other control measures, such as those already foreseen in the legislation, should be explored. These measures have been analysed under option 5.

7. ANALYSIS 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. Medicines will continue to be available to the public under the conditions established by national laws and practices. Therefore, consumers of these medicines will not be affected by any of these options.

No **environmental impact** can be associated with this problem. The only environmental aspect of the problem could be linked to the destruction of the medicinal products seized. However, these products will be subject to the same procedures and rules foreseen for the destruction of all seized goods in the Community Customs Code.

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 (the databases currently available are devised for commercial purposes and do not allow selecting this kind of information). However, SMEs were consulted as part of the pharmaceutical associations and also through the Enterprise Europe Network. From the absence of their replies and as confirmed by the pharmaceutical associations to which they belong, they are not much involved in the trade of medicinal products containing ephedrine or pseudoephedrine or are

[44] F. Horak, P. Zieglmayer,; R. Zieglmayer, P. Lemell, R. Yao, H. Staudinger, M. Danzig, (2009). "A placebo-controlled study of the nasal decongestant effect of phenylephrine and pseudoephedrine in the Vienna Challenge Chamber". *Annals of Allergy, Asthma & Immunology.*

working for the multinational companies that are active in this segment. Therefore, it could be assumed that SMEs as such would not be affected by this proposal.

International impacts: Diversion of drug precursors is a global problem which requires a global response. Therefore, control measures over drug precursors should be harmonized, to the extent possible, at international level so that weak controls in one country do not jeopardize the efforts of neighboring countries where controls may be more effective. In this respect international co-operation between the EU and third countries has a very significant role to play in preventing relevant chemicals from ending up in the illicit manufacture of drugs. 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. Annex 8 presents the data and methodology on how the additional administrative burden of the different options was calculated. The additional **administrative burden for the industry** could only be 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. Subsequent consultation with the Association of European Self-Medication Industry (AESGP) revealed that options 3 and 4 would not be opposed by the industry since the administrative burden on exporting companies would be minimal or even inexistent. They had initially feared that this proposal might have an impact on their sales and also limit the access to these medicines.

Options 1 to 5 are assessed in terms of their effectiveness in meeting the objective to prevent the diversion of medicinal products at stake for the illicit manufacture of methamphetamine. Three indicators have been used to determine the effectiveness of each option, namely the reduction of the supply of ephedrine and pseudoephedrine, the maintenance of the free flow of trade of ephedrine/pseudoephedrine medicines and the compliance with the international regulatory framework. Options 3, 4 and 5 are also assessed in terms of cost efficiency with the aim to avoid disproportionate administrative burden for competent authorities and the industry. Option 6, as previously mentioned, has been discarded and is not further assessed.

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

7.1.1. Effectiveness

In this option the identified weakness of the current legislation with regard to the diversion of medicinal products containing ephedrine and pseudoephedrine would remain, allowing traffickers to continue targeting medicinal products to source ephedrine and pseudoephedrine for the illicit manufacture of methamphetamines. 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**.

The seizures made over the past few years show fluctuation trends (as already shown in section **4.2 Scale of the Problem**). It can be assumed that these fluctuations may continue.

Diversion attempts concerning medicinal products containing ephedrine and pseudoephedrine have been experienced in the past to very different degrees by Member States. According to last years' EU statistics (2008 to 2010)[45], Austria, Bulgaria, Czech Republic, Finland, Germany, Sweden and UK are the most concerned Member States. Some of these countries have introduced control measures tailored to their needs. The argument has been made - mainly by the industry but also by some Member State authorities –that diversion is not a "European-wide" issue and the solution does not need to be enforced as a strict "European-wide" approach, which legislative amendments to the European drug precursor legislation would enforce. However, there is no demonstration of any impact of these national measures on external trade in these products, and on the extent to which they may have helped to prevent the exportation and diversion of such products to other countries. Moreover, such national measures do not address the problem of transit of pharmaceutical preparations containing ephedrine and pseudoephedrine through the EU territory. National measures tend to encourage traffickers to target their sourcing activities in Member States where no or little control measures are implemented. In addition, in the Single Market where goods circulate freely, the effectiveness of national control measures is limited since goods can be supplied from another Member State where such measures do not exist. Finally, problems related to the EU external trade in goods can only be addressed at the EU level.

At the same time, under this option, the **European Union will continue to be criticised at international level** for remaining "inactive" and for neglect of the continued calls by the INCB to step up legislative control of its external trade[46].

7.1.2. Cost efficiency

This option provides for no changes in the legislation, nor does it impose any additional administrative burden on European level on either businesses or national competent authorities. As there is no additional administrative burden and the “business as usual costs” will remain unchanged, the administrative costs will also remain unchanged.

7.2. Option 2: Recommending voluntary measures to Member States

7.2.1. Effectiveness

In this option, the Commission would suggest to Member States' competent authorities a set of measures which can be effective in preventing the diversion of these medicinal products. 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 methamphetamine (in one of the examples provided under option 6.2, in the Czech Republic purchase/sale of these medicinal products, after imposing restrictions, have dropped by 80% while not restricting legitimate access to those products).

In this option, if one Member State strengthens control over medicinal products containing ephedrine or pseudoephedrine, other Member States where no control measures over these products are in place will automatically be targeted by traffickers seeking to source the substances necessary for the manufacture of methamphetamines. The absence of a

[45] EU Annual reports: http://ec.europa.eu/taxation_customs/customs/customs_controls/drugs_precursors/seizures/index_en.htm

[46] INCB Annual Reports: 2008, 2009 and 2010.

homogeneous EU response will encourage traffickers to exploit potential differences of national control systems and will alter the level-playing field for economic operators who will be facing different requirements within the Union.

The trade flow of these products between the Union and third countries will not be affected. However, these specific products may be submitted to some restrictions on the market, depending on the measures taken.

It should be noted that the measures envisaged under this option would only address the aspect of exportation of medicinal products from the EU territory, not the transit cases.

Finally**, 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.

7.2.2. Cost efficiency

This option leaves the choice of which measure to be applied to the discretion of Member States, depending on the scale of the problem at national level. Whatever measure they may decide to implement, one can assume that it will imply some administrative burden at 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.

7.3. Option 3: Increasing the powers of competent authorities

7.3.1. Effectiveness

This option will establish within the drug precursor legislation a legal basis for Member States' competent authorities to stop[47] or seize a consignment of medicinal products containing ephedrine and pseudoephedrine in case they have doubts as to the legitimacy of the consignment.

Under this option, Member States' competent authorities will no longer need to look for other legal bases to stop or seize these products, such as national Drug Acts. The revised legislation will apply throughout the Union in the same way, thus providing consistency across Member States.

The creation of a tariff code at EU level for medicinal products containing ephedrine and pseudoephedrine will contribute to better targeting these goods for the purpose of controls.

This option will increase the chances to prevent diversion, thus reducing the supply of ephedrine and pseudoephedrine for the illicit manufacture of methamphetamines. This could result in a reduced offer of methamphetamine on the market, and reduce its abuse.

However, the effect would tend to be temporary as criminals will turn towards other precursors to manufacture methamphetamine or towards the manufacture of other drugs that can be produced with other substances which are not under international control. Medicinal products containing ephedrine and pseudoephedrine could also transit through other parts of the world between their place of origin and their final destination. Drug consumers could also turn their attention to other drugs more widely available.

[47] Stopping a consignment means that the delivery doesn't take place, the transaction (import/export) is not carried out.

The trade flow of medicines containing ephedrine or pseudoephedrine will not be hampered. Controls will be performed on these products in the same way as they are generally carried out on the precursors they contain, according to the general provisions of the Community Customs Code.

Moreover, **it will reduce the criticism expressed by the INCB** concerning the EU lack of action in imposing control measures over these products. By reducing the risk of diversion, the measure is expected to be positive for the third countries to which the goods are destined and where they may be used for the illicit manufacture of methamphetamines.

7.3.2. Cost efficiency

As this option would establish a clear legal basis for competent authorities to act over these products, controls will be performed both at export/import and in transit on the basis of risk analysis[48] as already used in respect of other sensitive goods internationally traded. 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 minimal.

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

7.4.1. 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 further minimise the risk of diversion by ensuring systematic and consistent monitoring of trade in drug precursors globally. The effectiveness of this system is proven by the growing number of notifications sent globally per year: 7900 notifications in 2007 increased to 25600 in 2010[49]. 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** which has repeatedly encouraged the Union to do so over the last years.[50]

The systematic use of PEN-online by Member States' authorities will also be welcomed by the international community as a whole and in particular by those countries[51] that have already introduced legislative measures making the use of pre-export notifications for this kind of products compulsory. Preventing the diversion of these products is considered a global problem which requires a global response. The more countries use PEN online, the more effective this tool will be, as this creates an unbroken chain of monitoring of international trade. This option will contribute to this international goal.

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48 Risk analysis in the context of Customs control is a working method that aims to maximise the use of Customs resources while minimising the risk. It aims to concentrate controls on goods of highest risk while at the same time leaving the majority of trade to flow relatively freely through Customs.

49 Source: extract from the PEN-online system by INCB.

50 INCB Annual Reports on Precursors: http://www.incb.org/incb/precursors_reports.html

51 Thailand, Malaysia and the United Arab Emirates

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 – to date 126 countries out of the 184 countries which are Parties to the 1988 UN Convention. This system provides for adequate monitoring: in cases where shipments are suspended, appropriate action is taken rapidly by all concerned to verify the legitimacy of an individual transaction[52]. Therefore, if its use were to be extended to medicinal products containing ephedrine and pseudoephedrine, it will not be an impediment to the legitimate trade. Moreover, no changes to the online system will be necessary as it already allows indicating whether the chemicals are in raw form or in the form of preparations.

Without the legal basis enabling competent authorities to stop and seize suspicious consignments (amendment of Article 26), the PEN system cannot be used to reduce the supply of precursors for the illicit drug manufacture.

7.4.2. Cost efficiency

The additional administrative burden for competent authorities in relation to the controls they will perform, under the amended Article 26, as explained under option 6.3, 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. This amount has been calculated on the basis of data provided by 12 Member States concerning the time spent on processing one PEN, the number of pre-export notifications sent per year and the hourly tariff per administration. It can be assumed that the additional administrative burden to send a pre-export notification for medicinal products containing ephedrine and pseudoephedrine would be the same as for any other substance of category 1, should these products be included in this category. The additional administrative burden will mainly depend on the volume of the licit trade for these products in each Member State.

However, it can be assumed that this additional administrative burden will be low and that it can be borne by Member States competent authorities given that over the last three years they have already been sending information voluntarily over the last three years during the international operational initiatives under Project Prism[53].

As previously mentioned, the additional administrative burden for the industry could not be assessed as no data were provided by the industry through the stakeholders' consultation. However, the pre-export notification is a task for competent authorities and not for the industry. This notification is filled in on the basis of the information already provided by the operators in the customs declaration they are obliged to submit prior to export. Once the authorities of the importing country have confirmed that the transaction is licit or for a maximum of 15 working days[54], the exportation can take place. The potential costs for the involved operators due to the delayed export are the same as any other potential costs they would incur should customs interrupt the transaction to perform controls such as those generally carried out on other goods submitted to other restrictive measure applicable to external trade.

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52 E/INCB/2011/WP.5 this document is confidential.

53 For the period of reference 2009-2011, nine Member States sent an average per year of 40 pre-export notifications for medicinal products containing ephedrine or pseudoephedrine

54 As established by Article 11 of Regulation No 11/2005. Further details under section 6.4

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

7.5.1. Effectiveness

This option will strengthen considerably controls over medicinal products containing ephedrine or pseudoephedrine, which are currently not controlled for the purpose of preventing their diversion, as they will be submitted to the same control regime imposed by the drug precursor legislation to the raw substances they contain. These substances are listed in Category 1, which covers the most sensitive substances ("key precursors"), as outlined in the Introduction to this initiative.

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

However, it has been argued by the industry and by some Member State's authorities that the requirements that would be applicable to these medicinal products in this option would be disproportionate to the objective pursued by the present initiative, considering that their diversion is not an EU-wide problem.

Moreover, **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.

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"*[55].

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

7.5.2. Cost efficiency

As medicinal products would be submitted to the same control regime as category 1 substances, the current and the additional administrative burden per requirement have been calculated on this basis.

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.

Licence (data available from 9 Member States' authorities). As the amount of licences issued per year varies significantly among Member States, the administrative burden for competent authorities to issue a licence for category 1 substances also varies considerably. The current average administrative burden per competent authority is € 861 per year.

[55] 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

It can be assumed that the additional administrative burden to issue a licence for medicinal products containing ephedrine and pseudoephedrine would be the same as for any other substance of category 1, should these products be included in this list. Given that currently the average time spent to issue a licence is 88 min and that the current average tariff of human labour per min is € 0,55, the current administrative burden to issue a licence is € 49. This figure should serve as a basis to assess the additional administrative burden for issuing licences, generated by the inclusion of medicinal products in the category 1 list, which ultimately depends on the volume of trade in those products in each Member State.

Import authorisation (data available for 10 Member States' authorities). As the amount of import authorisations per year varies significantly among Member States, the current administrative burden for competent authorities to grant an import authorisation for category 1 substances also varies considerably. The current average administrative burden per competent authority is therefore € 1236 per year.

As previously, it can be assumed that the additional administrative burden to grant an import authorisation for medicinal products containing ephedrine and pseudoephedrine would be the same as for any other substance of category 1, should these products be subjected to the same requirements. Given that the current average time spent to grant an import authorisation is 48 min and that the current average tariff of human labour per min is € 0.59, the current administrative burden to grant an import authorisation is € 28. This figure should serve as a basis to assess the additional administrative burden for granting import authorisations, which depends on the volume of trade in those products in each Member State.

Export authorisation (data available for 9 Member States' authorities). Likewise, the amount of export authorisations per year varies significantly among different Member States. Therefore, the current administrative burden for each Member State also differs. The average administrative burden per competent authority is € 995 per year.

Once more, it can be assumed that the additional administrative burden to grant an export authorisation for medicinal products containing ephedrine and pseudoephedrine would be the same as for any other substance of category 1, should these products be included in this category. Given that the current average time to grant an export authorisation is 51 min and that the current average tariff per min is € 0.56, the current administrative burden to grant an export authorisation is € 29. This figure should serve as a basis to assess the additional administrative burden for granting export authorisations, which depends on the volume of trade in those products in each Member State.

Due to the fact that a realistic forecast cannot be made without knowing the volume of trade in medicinal products containing ephedrine or pseudoephedrine per Member State, for the sake of this impact assessment, the calculations have been made on the assumption that 100 exports or imports of medicinal products are performed per year per competent authority (see Table 1. Comparing the options).

As far as **the industry** is concerned, despite the fact that no data were received, costs for obtaining the licence could be assumed on the basis of the licence fee charged by the competent authorities. The price range for the licence varies considerably among Member States, ranging from € 0 to as much as € 4348 (average: € 399). Moreover, the administrative burden per company to obtain a licence has been calculated in the framework of the impact assessment carried out by DG ENTR[56], this figure (€ 77) has been taken over in this impact

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

assessment. As costs for obtaining an import authorisation or an export authorisation were not notified in response to the consultation addressed to the industry, it may be assumed that these costs are marginal. As regards pre-export notification, as previously explained, this is primarily a task for competent authorities and not for the industry and, therefore, any burden for the industry will not be significant.

For the purpose of comparing the options, the additional administrative burden for competent authorities was calculated on the administrative costs generated by import and export operations. An export operation implies administrative costs for a licence (€ 49), for an export authorisation (€ 29) and for a pre-export notification (€ 15), while an import operation implies administrative costs for a licence (€ 49) and an import authorisation (€ 28). Thus the additional administrative burden of one competent authority dealing with one export operation is € 93. For an assumption of 100 operations, the administrative cost would be € 9300. For an import operation, the costs would be respectively € 77 and € 7700 as shown in Table 1. Comparing the options.

8. COMPARING THE OPTIONS

The following table has therefore been drawn in order to show 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***	++

* As the volume of trade is not known, these calculations have been made on the assumption on 100 pre-export notifications per year.

** As the volume of trade is not known, these calculations have been made on the assumption on 100 export operations (licence, export authorisation, pre-export notification), 100 import operations (licence and import authorisation) and 100 licences per year.

*** The same company only needs one licence independently from the number of transactions (import/export) they perform.

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.

Non-legislative measures, unless adopted across all Member States, would only partially address the identified problem. A compulsory application of these measures cannot be enforced by the instrument foreseen under option 2. 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. They 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 methamphetamines, 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 a legal basis, would impose only one extra control requirement and it would generate hardly any additional administrative burden.

9. MONITORING AND EVALUATION

9.1. Measuring the fulfilment of objectives

The Commission will continue to collect from Member States statistics of seizures and stopped shipment of medicinal products containing ephedrine or pseudoephedrine. These statistics will show whether under the new legislative measures a downward trend of seizures of diverted medicinal products and of stopped shipments (indicating diversion attempts) can be observed. A downward trend can also potentially imply that traffickers are avoiding the EU customs territory, as a consequence of strengthened measures on that territory. Comparing the amount of medicinal products seized or stopped to the overall quantity of medicinal products containing ephedrine or pseudoephedrine traded between the EU and third countries will be a first indicator of the percentage of diversion of these products. This will be possible as from 2013 at EU level when the relevant tariff codes will be created in the Combined Nomenclature and as from 2017 at global level when the same codes will be created in the Harmonised System. Moreover, the Commission, in cooperation with Member States, will collect annually the number of pre-export notifications sent by competent authorities for these products, including details about the quantities and the countries where the products were destined. These progress indicators are outlined in Annex 5.

9.2. Monitoring the implementation of the new legislative measures

Should Regulation (EC) No. 111/2005 be amended, the Commission will ensure that the system put in place is monitored in order to assess its correct functioning. This will be achieved through the following mechanisms.

9.2.1. Collecting, analysing and publishing statistics

As in previous years, the Commission will analyse the data provided by EU Member States which forward results relating to the licit and illicit trade of drug precursors to the Commission on a quarterly basis and will report yearly on statistics of customs seizures of precursors used in the illicit manufacture of drugs. These data also include medicinal products containing ephedrine or pseudoephedrine, thus allowing assessing if a downward trend of diversions of these products is achieved in the short term and maintained in the long term. In order to evaluate to what extent the new legislative measures contribute to the operational objective of reducing the number of attempts to divert medicinal products containing ephedrine or pseudoephedrine, the Commission will request Member States' competent authorities via the Drug Precursors Working Group to collect data concerning the number of notifications of suspicious transactions, as well as the number of pre-export notifications sent for transactions involving medicinal products containing ephedrine or pseudoephedrine

The system will be improved with the implementation of an electronic system, which is currently being developed by the Commission that shall facilitate the collection and analysis of statistics. This system is scheduled to become operational in the beginning of 2013.

The European Commission has undertaken to create new tariff codes for medicinal products containing ephedrine and pseudoephedrine in the Combined Nomenclature, through the Customs Code Committee, Tariff and Statistical Nomenclature section, in accordance with the relevant Rules of Procedure, which will allow determining the volume of trade (import and exports) of these specific products.

9.2.2. Monitoring difficulties in the implementation

The Drug Precursors Working Committee, composed of the Member States and the Commission, will continue to analyse any issue related to the implementation of the Regulation, including the new measures it will provide for.

9.2.3. Involvement of stakeholders

The Commission will ensure that all stakeholders are given the opportunity to express their views and concerns with regards to the application of the Regulation, including the new measures it may provide for, through the appropriate channels. In particular, the stakeholders (pharmaceutical industry) will be invited to participate in a meeting of the Drug Precursors Working Group/Committee together with the Commission and representatives of Member States.

9.2.4. Supporting the implementation of the new legislative measures

The Commission will develop, together with Member States experts and interested stakeholders, a number of accompanying activities to facilitate the implementation of the new measures.

9.2.5. Guidelines

The Commission will update existing guidelines for the implementation of the Regulation by competent authorities and economic operators.

9.2.6. Activities

The Commission will organise awareness-raising activities involving both competent authorities and economic operators as described under section 6.2 outlining the non-legislative option.

9.3. Monitoring results and exchange information with the third countries concerned

To maximise the impact of the measures proposed, it would be useful to continue the exchange of information and trends with the governments of third countries, in particular those concerned by the production and consumption of methamphetamines. For example, the Commission is in the process of re-launching the cooperation with Latin American countries under the existing bilateral agreements on the control of drug precursors. This cooperation will offer the opportunity to evaluate the effectiveness of the measures taken at EU level and assess whether the EU continues to be a transit platform for medicinal products containing ephedrine and pseudoephedrine destined to Latin America. Continued dialogue with the US and China will also be pursued on this matter.

9.4. Overall evaluation

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.

10. ANNEX

Annex 1: Stakeholders' questionnaires

Annex 2: Summary of stakeholder consultation

Annex 3: Guidelines for operators (page 8)

Annex 4: Ephedrine/Pseudoephedrine Laws in Central America

Annex 5: Objectives

Annex 6: Drug legislation in the Member States

Annex 7: Articles 2(a), 11 and 26 of Council Regulation (EC) No 111/2005

Annex 8: Methodology for calculating the additional administrative burden of the options