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Analysis of the New European Legislative Measures Adopted in the Field of Drug Precursors

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ABSTRACT: Drug precursors are chemicals that are primarily used for the legal production of a wide range of products such as medicines, perfumes, plastics, cosmetics, etc. However, by diversion from the licit circuit, these chemicals can be used for the illicit production of drugs. Given the wide range of legitimate uses of drug precursors, their trade cannot be banned. To prevent the diversion of precursors from licit channels, specific rules have been put in place at both international and EU levels to control their legitimate trade at EU borders and on the internal market. European legislation on precursors aims to strike a balance between the control needed to prevent their diversion and their legitimate trade and use, without creating unnecessary administrative burdens. This article aims to analyze the legislative measures taken at EU level to monitor the trade in drug precursors between the Union and third countries and the harmonization of the national legislative framework in this area. It also aims to analyze the effectiveness, efficiency, relevance and coherence of the legislative framework on drug precursors and how this is integrated into EU drug policy.

KEYWORDS: EU legislation, drug precursors, internal market, legitimate trade, unscheduled substances

Introduction

Drug precursors are chemicals that are primarily used for the legal production of a wide range of products such as medicines, perfumes, plastics, cosmetics, etc. However, by diversion from the licit circuit, these chemicals can be used for the illicit production of drugs. Given the wide range of legitimate uses of drug precursors, their trade cannot be banned. However, to prevent the diversion of precursors, specific rules have been put in place at both international and EU levels to control their legitimate trade at EU borders and on the internal market.

Legislation on drug precursors aims to strike a balance between the control needed to prevent their diversion and their legitimate trade and use, without creating unnecessary administrative burdens. The manufacture of illicit drugs such as heroin, cocaine and amphetamines requires the use of chemicals. However, these chemicals primarily have wide and diverse legitimate uses, for example, in the production of pharmaceuticals, cosmetics, plastics and perfumes. These chemicals are referred to as drug precursors. Drug precursors are rarely produced by criminals who intend to use them in illicit drug manufacture, as their production often requires a substantial infrastructure.

Theory

The trade in drug precursors is not in itself prohibited because of the wide range of legitimate uses. Effective monitoring and control of legitimate trade in these chemicals is the best way to combat their diversion into illicit drug manufacture. To this end, a specific regulatory framework has been put in place at both international and EU levels.

At international level, the UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances was adopted in Vienna on 19 December 1988 and contains provisions aimed at preventing the diversion of substances commonly used in the illicit manufacture of drugs.

At EU level, Regulation (EC) No 111/2005, Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors and their joint delegated and implementing regulations have been enacted for this purpose.

Regulation (EC) No 111/2005 lays down rules for monitoring trade in drug precursors between the European Union (EU) and third countries. It applies to the import, export and transit of drug precursors in order to prevent their diversion.

The objectives of this regulation are:

- to introduce import and export licensing requirements for targeted drug precursors;
- to require all operators to label and attach appropriate documentation to drug precursors;
- to require all operators to be authorized;
- to ensure that all batches of drug precursors are inspected within the EU;
- to tighten import and export controls;
- to conduct special EU-wide controls in high-risk diversion areas, such as free zones and transhipment zones.

Member States must provide the competent authorities with the means to obtain the information and carry out the investigations necessary to prevent diversion. Mutual assistance and confidentiality between Member States' administrations are essential. Member States shall lay down appropriate penalties for infringements of the provisions of the Regulation. Each year they send the Commission the results of the monitoring measures, based on which the Commission draws up an annual report to be submitted to the International Narcotics Control Board.

The Commission also draws up guidelines for the chemical industry, including information on how to recognize and report suspicious transactions and an updated list of unscheduled substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

Results and discussions

Although Regulation (EC) No 273/2004 concerns internal trade and Regulation (EC) No 111/2005 concerns international trade, many of the provisions are common to both Regulations. To ensure consistency, a single delegated act has been adopted covering and complementing both Regulations, Delegated Regulation (EU) 2015/1011.

To ensure legal clarity and consistent application across EU states, the Regulation defines the term commercial space as the building(s) and land that an operator occupies at every single site. The necessary authorizations and registrations for operators intending to carry out activities involving drug precursors which may be used for the illicit manufacture of narcotic drugs or psychotropic substances are granted only to reliable operators who so request. To receive the authorization, operators must implement appropriate measures to ensure the safe treatment and storage of these drug precursors and appoint an identifiable responsible person to ensure that activities involving these substances are carried out in accordance with the relevant legal provisions.

The Regulation exempts from the requirement to hold an authorization or registration to carry out activities involving drug precursors certain operators dealing with drug precursors for medical use, such as pharmacies and veterinary practices, as well as certain public authorities.

Operators engaged in activities involving drug precursors which are not intended for the Union market but have been introduced into the EU customs territory must provide information showing that the export of these substances has been carried out in accordance with the relevant international conventions, to demonstrate the licit purposes of the related transaction.

In addition, to facilitate the monitoring by competent authorities of the trade in drug precursors, the Regulation requires operators established in the EU to provide certain basic information on the activities they have carried out. To minimise the risk of diversion of certain drug precursors, their export must be preceded by a pre-export notification and an

export authorization. In order to reduce the administrative burden for trade in certain categories of drug precursors, the Regulation lays down a simplified procedure for the pre-export notification and the export authorization.

As there are frequent changes to the lists of third countries of destination for the export of substances listed in categories 2 and 3 of the Annex to Regulation (EC) No 111/2005 and to allow for a timely update of these lists in accordance with the criteria for them set out in the new Regulation, these lists will be published on the Commission's website. Delegated Regulation (EU) 2015/1011 requires Member States to regularly submit to the Commission information on seized or confiscated drug precursors, precisely in order to improve the coordination of the implementation of the regulated monitoring measures.

Implementing Regulation (EU) 2015/1013 lays down uniform rules for the implementation of Regulations (EC) No 273/2004 and (EC) No 111/2005 as regards the authorization and registration of operators and users and their inclusion in the European database on drug precursors, the provision by operators of information necessary for the monitoring of trade and of export and import licences for drug precursors.

Combating the diversion and trafficking of drug precursors is one of the objectives of the EU Agenda and Action Plan on Drugs 2021-2025. These measures are included in the global strategic priority of improving security by disrupting drug markets. Since both Regulations (Article 16 (3) of Regulation (EC) No 273/2004 and Article 32 (4) of Regulation (EC) No 111/2005) lay down the requirement that by 31 December 2019, "The Commission shall report to the European Parliament and the Council on the implementation and functioning of this Regulation and, in particular, on the possible need for further action to monitor and control suspicious transactions in unscheduled substances." The implementation, effectiveness, efficiency, relevance, coherence and EU-added value of the Regulations were assessed in the period 2017 - 2019.

The report on the evaluation of the drug precursor regulations was supported by a study commissioned by the Commission from an external contractor, and stakeholder and public consultations, interviews and a stakeholder workshop were also organised. The evaluation found that the Drug Precursors Regulations are directly applicable in the Member States and therefore there is no need for the Member States to transpose them into their national legislation.

The most important actors in preventing the diversion of drug precursors are the operators involved in the legal trade (manufacturers, distributors, brokers, importers, exporters, and wholesale distributors). The legislation requires them to take measures against theft, check the good faith of their customers, detect suspicious transactions, and alert the authorities. The Commission, therefore, believes that an effective partnership between the industry and the authorities is the cornerstone of the implementation of the regulatory framework.

The evaluation revealed that a potential consistency problem is caused by the fact that a particular substance, gamma-butyrolactone (GBL), is both a drug precursor and a drug in its own right. The ambiguous status of the substance has led to a situation where it is regulated in very different ways from one Member State to another. Several substances have also been identified as being classified as drugs in the narcotics legislation at Member State level and as drug precursors in the regulations. By themselves, these issues do not affect the effectiveness of the Regulations, but in some cases may cause problems in terms of the integrity of the EU internal market. However, this is not due to the provisions in the Regulations themselves, nor is it possible to eliminate this threat by amending the Regulations. Indeed, substances included in the schedules of the 1988 UN Convention must remain classified in the drug precursor regulations, regardless of whether some of them are considered drugs (and treated as such) by some Member States. From the point of view of the Regulations, it is important to ensure that substances are classified according to consistently applied criteria, although this

cannot be assured with absolute certainty, given the legal obligations arising from the text of the 1988 UN Convention.

In its report to the European Parliament and to the Council, the Commission showed that the main drug precursors for amphetamine and MDMA production in the EU are now almost exclusively modified precursors. Modified precursors are chemically close relatives of a scheduled drug precursor, which are specially manufactured to avoid control by the authorities and usually have no known legitimate use. In addition, methamphetamine is also often produced in the EU based on the main precursors, ephedrine and pseudoephedrine. In many cases, these are extracted from medicines containing these substances which have been legally purchased, without prescription, in pharmacies in certain Member States. In other words, these precursors are not 'diverted' in the traditional sense of the word either.

In addition to the main drug precursors, the production of synthetic drugs in the EU also requires large quantities and different types of ancillary drug precursors, such as reagents, solvents, separating or dispersing agents, which are used during chemical synthesis but are not incorporated into the drug.

Because these chemicals are usually produced and traded in very large quantities, preventing their diversion from licit channels is particularly difficult. Even if the overwhelming majority of operators fully comply with the regulations, it only takes a very limited number of careless or corrupt operators to supply the necessary ancillary drug precursors to illegal drug producers. In view of these issues, with regard to the manufacture of synthetic drugs in the EU and in the case of ancillary substances, the prevention of diversion of drug precursors has not been effective in the EU through the enforcement of the regulations.

In terms of domestic legislation, Law No 142 of 18 June 2018 regulates the legal regime of substances frequently used in the illicit manufacture of narcotic and psychotropic substances. The law contains provisions on the legal regime of drug precursors and lays down the necessary measures to implement at the national level the provisions contained in the Delegated Regulation (EU) 2015/1011 and the Implementing Regulation (EU) 2015/1013.

The competent authority in the field of precursors is the National Anti-Drug Agency under the Ministry of Internal Affairs, which performs the following main functions:

- monitors operators and operations with scheduled and unscheduled substances in order to ensure the legality of operations with drug precursors and applies, for this purpose, the administrative control measures provided for by law;
- coordinates, at the national level, the activities carried out by the national authorities and institutions responsible for preventing the diversion of drug precursors;
- ensures cooperation with the civil society and with international authorities and bodies in the field of drug precursors, by organising or participating in meetings or working groups with their representatives, information, data exchange and any other activities necessary to carry out its specific functions;
- sets up and manages the national database on drug precursors under the conditions laid down in the implementing regulation;
- constitutes the single contact point in accordance with Article 12 of Implementing Regulation 2015/1013;
- forwards to the European Commission the communications referred to in Article 13(1) of Regulation (EC) No 273/2004 and of Article 32(1) of Regulation (EC) No 111/2005 under the conditions laid down in Article 13 of the Delegated Regulation 2015/1011. The contact of operators and users of drug precursors with the relevant national authorities, to fulfil the obligations provided for in this Law, shall be carried out through the specialised structure of the National Anti-Drug Agency, which shall act as a one-stop shop for drug precursors.

The National Anti-Drug Agency shall ensure that operators of drug precursors are made aware of the guidelines drawn up by the European Commission, provided for in Article 9 of Regulation No 273/2004, and of the guidelines in Regulation No 111/2005, as well as of the list of unscheduled substances, by any means it deems appropriate to fulfil its purpose.

In application of Article 10(4) of Regulation No 111/2005, the National Anti-Drug Agency, after consulting, where appropriate, with the relevant national authorities, may propose to the European Commission to add an unscheduled substance to the list referred to in Article 10(2) letter b) of Regulation No 111/2005.

To verify the legitimacy of operations with drug precursors or the reality of the data contained in the applications made by operators or users of drug precursors, the National Anti-Drug Agency may request relevant data and information from public or private entities holding such data.

The control of compliance with the legal regime of drug precursors, including at the premises of operators and users, shall be exercised by the National Anti-Drug Agency, the General Inspectorate of the Romanian Police, the General Inspectorate of the Border Police or their subordinate units, as appropriate, as well as by the competent customs authority, in accordance with their duties in their areas of activity.

Conclusions

The Regulations apply to drug precursors which are defined as 'scheduled substances' and which are included in the annexes to the Regulations. However, they also contain some provisions that apply to 'unscheduled substances', in particular the need to report suspicious transactions to the authorities. Unscheduled drug precursors are substances that, although not covered by EU drug precursor legislation, can be used to manufacture illegal drugs. The most commonly used unscheduled substances are included in the EU voluntary monitoring list of unscheduled substances. This list is confidential and is distributed only to trusted economic operators, who are asked to report to the authorities any suspicious transactions involving substances on the list.

Chemical substances are 'scheduled' (formally included in regulations) when the cost of classification to operators and competent authorities does not outweigh the benefits of stricter control or because the substance can easily be diverted to the manufacture of illegal drugs. The European Commission's assessment showed that the implementation of the drug precursor regulations varies considerably between Member States. This is the result, among other things, of varying staff resources allocated to these tasks by different Member States, of significant differences in the frequency of on-the-spot checks carried out on authorization or registration holders, of different interpretations of the definition of mixtures containing drug precursors, of the level of penalties applicable in the event of infringements of the regulations, and of significant differences in the number of suspicious transaction reports from different Member States.

However, a significant degree of variability is likely to be due to the existence of specific circumstances at the Member State level. For example, there are considerable differences between Member States in the scale and level of development of chemical industries. In addition, the scale of illicit drug production varies greatly between Member States, which has an impact on the importance given to drug precursor policy.

In addition, the wide differences in the illicit drugs that cause the most health and social harm also explain why Member States pay different attention to the monitoring of certain drug precursors. For example, a Member State where illicit methamphetamine production or use is non-existent or marginal may not give high priority to monitoring the drug precursors needed for illicit methamphetamine production.

As there are considerable differences in Member States' legislation in terms of sanctions applied for violations of EU drug precursor legislation, EU authorities need to pay

close attention, in particular, to assess whether sanctioning measures are dissuasive, effective and proportionate.

Given that the diversion of and trafficking in drug precursors is a global phenomenon which also requires international cooperation, the current EU drug precursor control and monitoring regime can no longer successfully respond to the overall societal needs it was designed to meet.

References

Commission Delegated Regulation (EU) 2015/1011 of 24 April 2015 supplementing Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Union and third countries in drug precursors, and repealing Commission Regulation (EC) No 1277/2005, published in the Official Journal of the European Union, L 162 of 27 June 2015.

Commission Implementing Regulation (EU) 2015/1013 of 25 June 2015 laying down rules on Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and of Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Union and third countries in drug precursors, published in the Official Journal of the European Union, L 162 of 27 June 2015.

Council of the European Union, General Secretariat, *EU Drugs Strategy 2021-2025*, Publications Office of the European Union, Brussels, 2021, ISBN 978-92-824-7960-5, doi:10.2860/802362.

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, published in the Official Journal of the European Union L 22 of 20.1.2005.

European Commission. 2020. Report from the Commission to the European Parliament and the Council: *Evaluation of the EU drug precursor regulations*, Brussels, 30.11.2020 COM (2020) 768 final.

Law No 142 of 18 June 2018 on drug precursors, published in the Official Gazette No 519 of 25 June 2018.

Regulation implementing Law No 142/2018 on drug precursors of 18.04.2019, published in the Official Gazette No 360 of 9 May 2019.

Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors, published in Official Journal of the European Union L 47 of 18.2.2004.