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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2025) 399 final
Subject:	COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on monitoring and controlling drug precursors and repealing Regulations (EC) No 273/2004 and (EC) No 111/2005

Delegations will find attached document SWD(2025) 399 final.

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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

on monitoring and controlling drug precursors and repealing Regulations (EC) No 273/2004 and (EC) No 111/2005

{COM(2025) 747 final} - {SEC(2025) 328 final} - {SWD(2025) 397 final} - {SWD(2025) 398 final}

Executive Summary Sheet
Impact assessment on a proposal for a regulation of the European Parliament and of the Council on drug precursors
A. Need for action
What is the problem and why is it a problem at EU level?
The evaluation of Regulations (EC) No 273/2004 and (EC) No 273/2004 (the EU drug precursor regulations) identified some deficiencies in them. On the one hand, drug precursors continue to be available for the illicit production of drugs. This increasingly concerns designer precursors. These are substances that can be used as precursors and do not have a known legal use other than research and innovation. On the other hand, economic operators engaged in the legal trade in the substances, as well as public authorities, have to contend with unnecessary burdens and inefficiencies in performing their activities.
What should be achieved?
This initiative should reduce the availability of drug precursors for illicit drug production. It should also facilitate the legitimate trade in and use of drug precursors.
What is the value added of action at EU level (subsidiarity)?
The two EU drug precursor regulations set the rules for the legitimate trade in chemical substances, in the EU and with non-EU countries, that can also be used in illegal drug production. The monitoring and control of trade between the EU and non-EU countries falls under a policy area in which the EU has exclusive powers and to which the subsidiarity principle therefore does not apply. For the internal market, any changes to the scope or requirements of such rules must be made at EU level to avoid: (i) distorting the market; (ii) creating barriers to the free movement of goods or (iii) undermining efforts to prevent the diversion of drug precursors.
B. Solutions
What are the various options to achieve the objectives? Is there a preferred option or not? If not, why?
In addition to the baseline of no action, the impact assessment identifies three policy options. **Policy option 1** proposes technical adaptations to address the problems by providing guidance on substances and mixtures, such as a library of substances. In accordance with an agreement with the Parliament and Council, adding substances to the regulations would be sped up. Controls of scheduled designer precursors would be adapted to focus on the need to prove legitimate use and to enable the use of small quantities for research purposes. For external trade, rules would remain the same so that imports would continue to be controlled. Reporting obligations for internal trade would be simplified. **Policy option 2** would entail a comprehensive review of the rules and a merging of the two drug precursor regulations. Substances would be subject to control regimes using the comitology urgency procedure. A new regime to ban a moderate range of designer precursors would be introduced, with exemptions if authorities are given advance notice. Larger quantities would require a licence. The obligations of economic operators would be adapted to reflect the risk of various transactions, avoid creating loopholes in the control regime and avoid imposing an unnecessary burden. Procedures would be fully digitalised. **Policy option 3** would be a comprehensive review with a stronger focus on controls, also including a merging of the two drug precursor regulations. More emphasis would be placed on preventing diversion, with the result that a wider range of designer precursors would be included within the control regime. A more limited number of obligations for economic operators would be lifted while, depending on the substance, some additional obligations would be introduced. Procedures would be fully digitalised. These policy options would be accompanied by a set of flanking measures intended to improve the implementation of rules and strengthen EU countries' enforcement capacity (e.g. compliance checks and assistance with testing capacity). The **preferred policy option is option 2** as it addresses the risks of designer precursors and diversion without hampering legal trade, innovation and research. Policy option 1 was considered to have a very limited impact on the achievement of both objectives. The scope of policy option 3 was considered too broad, and the cost of the

attendant controls considered too high, to result in a reasonable cost benefit balance for the achievement of both objectives.

What are different stakeholders' views? Who supports which option?

Industry stakeholders welcomed the measures under option 1 but there was more support for the burden reduction and digitisation measures under policy option 2. Industry welcomed better and more targeted controls of designer precursors but highlighted the need for clear and unambiguous identification of the substances that fall under the scope of the legislation. They were opposed to some of the additional control measures under option 3.

Again, EU countries welcomed the measures under option 1 but preferred the regulatory measures under option 2. They expected administrative cost savings would arise out of these. EU countries were less critical of the tighter control measures that would be introduced under option 3, but also pointed out that option 3 might entail very high enforcement costs.

C. Impacts of the preferred option

What are the benefits of the preferred option (if any, otherwise the main ones)?

The impact assessment considers that policy option 2 would lead to a substantial decline in the trafficking of designer precursors and other non-scheduled precursors (for two years based on similar previous measures) and a more robust supply chain control system.

Option 2 would also entail quicker and more efficient processes that would be more harmonised and less prone to error. Lower compliance costs for economic operators to fulfil specific obligations and the removal of compliance costs for the fulfilment of certain obligations (overall annual costs would be down EUR 25.27 million compared to the baseline) and hassle costs would also be reduced. At the same time, public authorities would benefit from more efficient processes that would reduce licence application/registration costs by 25-50% and would reduce them altogether for export/import and annual reporting.

Licence application and registration costs would be reduced (recurring costs would fall by approximately EUR 72 000/year and one-off costs by just over EUR 250 000), while the digitalisation of customer verification would reduce costs by EUR 17.6 million/year. Import/export authorisation costs (approximately EUR 6.4 million/year) and annual reporting costs (EUR 3.2 million/year) would be eliminated.

What are the costs of the preferred option (if any, otherwise the main ones)?

The preferred option would entail an investment in a new IT infrastructure which would amount to EUR 17-26.6 million, and an additional annual cost for EU countries of about EUR 1.38 million. A repository managed by the European Drug Agency would cost 1 full-time equivalent + EUR 182 000, while there would be higher enforcement costs for EU country authorities (+30%) to fully implement rules in the online environment.

Due diligence administrative costs for economic operators linked to the ban on designer precursors would amount to EUR 7.7 million (one-off), assuming a list of 150 substances. Moderate additional costs are estimated to be +10% for EU countries to implement the ban.

What are the impacts on SMEs and competitiveness?

Policy option 2 would enable small and medium-sized enterprises (SMEs) to reap the benefits of the digital age by streamlining procedures and reducing hassle costs (such as waiting times for import and export authorisations). It would also reduce the burden for both SMEs and larger companies. The rules on designer precursors would be designed so as not to hamper research and innovation. Policy option 2 should therefore also have a positive impact not only on competitiveness for SMEs, but also for the EU economy as a whole.

Will there be significant impacts on national budgets and administrations?

EU countries may face some adaptation costs to adjust to new procedures, especially IT procedures, estimated to be EUR 1.38 million annually. They will benefit from the removal of reporting requirements and from streamlined administrative procedures. The scheduling designer precursors is expected to lead to some enforcement costs.

Will there be other significant impacts?

No other significant impacts have been identified.

Proportionality?

The preferred option does not exceed what is needed to achieve the objectives. It will clearly set out and

facilitate the rules for legal trade in drug precursors.
D. Follow-up
When will the policy be reviewed?
The new regulation will be evaluated 10 years after its entry into application.