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Opinion of the European Economic and Social Committee

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 – 2025/0384 (COD))

(C/2026/3550)

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Legislative procedure	EU Law Tracker
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Legal basis	Articles 114 and 304 of the Treaty on the Functioning of the European Union
European Commission documents	COM(2025) 747 final – 2025/0384 (COD) Summary of COM(2025) 747 – 2025/0384 (COD)
Relevant Sustainable Development Goals (SDGs)	SDGs 3, 9 and 16
Section responsible	Single Market, Production and Consumption
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1. RECOMMENDATIONS

The European Economic and Social Committee (EESC) recommends the following:

1.1. **ensure** that access to the 'Drug Precursors Information Repository' (Article 25) is entirely free of charge, providing digital tools that allow for the immediate identification of Category 3 substances;

1.2. **provide** for total exemptions or significant reductions in fees to issue licences (Article 9) for universities, research institutes and philanthropic organisations, to avoid depleting funds intended for scientific advancement;

1.3. **streamline** the prior notification procedures for the use of small quantities of 'designer' precursors (Article 17), ensuring that bureaucratic timelines do not hinder urgent medical and pharmacological research projects;

1.4. **establish** a dedicated technical guidance channel for all stakeholders, including third sector organisations, with rapid clarification on the classification of substance variants;

1.5. **avoid** legal uncertainty for research laboratories caused by the generic inclusion of substance groups in Category 3 by publishing clear, timely, and exhaustive exemption lists for substances with proven scientific value (Article 37);

1.6. **involve** civil society organisations specialised in addiction prevention and harm reduction in awareness-raising and training activities, integrating their field experience with the technical expertise of customs authorities (Article 26);

1.7. **apply** the obligation to appoint a 'responsible officer' (Article 10) with flexibility for small civil organisations, allowing for the designation of existing internal staff to avoid the burden of additional high-cost hiring;

1.8. **achieve** homogeneous regulation in the EU. This will support authorities in tracking substance trading and the use of substances in research all across Europe. Regulation which is not homogeneous is a significant barrier to innovation and development and complexity in sourcing the necessary substances (in research);

1.9. **protect** the autonomy of researchers using Category 3 precursors by ensuring that competent authority controls (Article 28) are risk-based and do not interfere with the confidentiality or integrity of scientific research protocols;

1.10. **promote** close collaboration between the Commission and the third sector, scientific organisations, pharmaceutical industry associations and general chemical associations during the ten-year review of the Regulation to evaluate whether restrictions on Category 3 substances have unintentionally slowed down legitimate therapeutic discoveries (Article 41).

2. EXPLANATORY NOTES

Horizontal arguments

2.1. The rise of numerous new psychoactive substances (NPS) requires the outdated 2005 control model to be replaced with a flexible regulatory system that ensures open data access and protects scientific research, as precursor monitoring is intrinsically linked to the risk of them being diverted for NPS synthesis. While the Regulation primarily addresses trade, Article 26 provides a strategic framework to enhance customs effectiveness by involving civil society and harm reduction organisations; this inclusion closes a critical knowledge gap by integrating logistical expertise with real-time field data on emerging substance patterns, creating essential operational synergy to prevent illicit trafficking and protect European public health.

Arguments in support of recommendation 1.1

Article 25's Drug Precursors Information Repository should function as a public knowledge tool, not merely a state surveillance instrument. Given the rapid expansion of over 1 000 new psychoactive substances, transparency is essential to help researchers and frontline services detect emerging chemical risks in real time.

2.2. Bridging the 'window period': providing free and simplified digital tools is essential to shorten the dangerous 'window period' that exists between the creation of a new substance, its market entry and its potential legal classification.

2.3. Response to evolving trends: open access to the repository helps scientists track evolving substances and emerging chemical mixes like methamphetamines and synthetic opioids

2.4. Supporting public health sensors: by ensuring stakeholders have the tools for immediate substance identification, the repository empowers frontline services to act as effective sensors for public health, detecting unknown substances that may not yet be scheduled.

Arguments in support of recommendation 1.2

Requiring fees for licenses may hinder scientific innovation at a time when rapid research is crucial to respond to evolving drug market.

2.5. Protection of research funds: exempting or reducing fees for universities and research institutes ensures that economic resources are dedicated to scientific advancement and public health rather than administrative costs.

2.6. Countering substance variability: as the market has exceeded 1 000 new psychoactive substances (NPS), it is vital for research centres to be able to operate without economic barriers to promptly identify new mixtures and complementary precursors.

2.7. Supporting proximity sensors: harm reduction services act as early sensors; licensing costs reduce their ability to detect new substances.

2.8. Reducing bureaucratic obstruction: facilitating access to licenses allows for a more agile response to the laboratory manipulation of methamphetamines and opioids, reducing the dangers associated with 'window periods' when substances circulate unregulated.

Arguments in support of recommendation 1.3

Article 17's rigid notification rules reflect an outdated 2005 framework and do not match today's rapidly evolving 'pseudo-legal' substances; regulation should shift toward faster, science-led monitoring that can keep pace with illicit innovation.

2.9. Combating 'window period' impunity: streamlining procedures is the only way to intervene during the temporary periods where new, unregulated substances circulate without legal consequences.

2.10. Decoding the 'precursor-product' blur: modern illicit production uses a 'mix' of substances where the role of excipients and complementary chemicals is constantly changing; barriers to research must be removed to redefine these roles as they evolve.

2.11. Institutionalising the 'frontline sensor' model: speeding up procedures allows harm reduction services to act as effective detectors, transforming their proximity to consumption sites into a real-time toxicological early-warning system.

2.12. Technical agility for public health: instead of traditional tabulation, which is always late, streamlined notification empowers labs to provide immediate alerts on the specific toxicity of new mixtures before they cause mass harm.

2.13. Proportionality for small quantities: for small research quantities, notification should occur at use, ensuring traceability without halting lab work.

2.14. Synchronization with public health alerts: an accelerated procedure allows scientific data to be fed into EU early warning systems as soon as a threat is detected, without having to wait for bureaucratic timelines to lapse.

Arguments in support of recommendation 1.4

Establishing an integrated communication and monitoring network (Article 35). The proposed IT system must evolve from a mere database into a dynamic platform for information exchange. Given that the drug landscape has shifted toward high-speed laboratory innovation, static regulatory barriers are no longer effective.

2.15. A networked response to NPS: establishing a dedicated channel allows for the creation of a European digital space where frontline services can report the specific harmfulness and composition of new substances in real time.

2.16. Bridging the information gap: rapid technical assistance ensures that administrative delays do not prevent researchers from studying the 'transformative effects' of methamphetamines and synthetic opioids as they emerge.

2.17. Reducing 'pseudo-legal' windows: by integrating stakeholders through a centralised system, the Union can accelerate the identification of new mixtures, significantly shortening the time between a substance's appearance and its regulation.

2.18. Promoting public health safety: facilitating constant dialogue between the scientific community and regulators helps mitigate the risks connected to the illegal market entry of highly toxic substances like fentanyl analogs.

2.19. Addressing classification ambiguity: a dedicated channel clarifies whether a research molecule falls under the regulation, preventing ambiguity from stifling innovation.

2.20. Support for Non-Industrial Users: while industrial uses are well-mapped, research involves high-variability molecules; technical assistance ensures that small-scale research entities can navigate the complexities of delegated acts and substance grouping without requiring expensive legal departments.

Arguments in support of recommendation 1.5

Countering legal uncertainty in the NPS era (Article 37): generic categorisation creates a 'chilling effect' on innovation precisely when the high variability of the market (over 1 000 NPS) demands more intense scientific vigilance.

2.21. Preventing scientific paralysis: exhaustive exemption lists are vital to ensure laboratories do not abandon studies on new molecules due to fear of liability, which would leave 'pseudo-legal' substances to circulate without oversight.

2.22. Decoding complex chemical mixes: as substances frequently shift roles between active components and excipients, researchers require absolute legal clarity to analyse these transformations without the risk of misinterpretation.

2.23. Neutralising regulatory lag: clear parameters allow for the immediate verification of chemical compositions, accelerating the detection of dangerous new variants (such as fentanyl analogs) before they achieve mass diffusion.

2.24. Transparency for proximity sensors: a well-defined classification system enables frontline services to accurately report the specific harmfulness of new laboratory variants to the European monitoring network.

Arguments in support of recommendation 1.6

While the Regulation primarily monitors trade, Article 26 provides a strategic framework to enhance customs effectiveness through stakeholder engagement. The inclusion of civil society and harm reduction organisations addresses a critical 'knowledge gap' by integrating logistical expertise with real-time data on emerging substance patterns. This operational synergy is not outside the Regulation's scope but essential to fulfilling its objective of preventing precursor diversion and protecting public health.

2.25. Utilising proximity sensors: civil society groups act as early detectors, helping authorities identify harmful new drug mixtures before standard seizures.

2.26. Contextualizing chemical trends: while customs focus on substance identification, harm reduction specialists provide the necessary context on how these 'pseudo-legal' compounds are actually being used, helping to predict future shifts in precursor demand.

2.27. Closing the response gap: collaboration between technical experts and field workers shortens the 'window period' of unregulated circulation by facilitating the rapid flow of toxicological data from the street to the regulatory level.

2.28. Evidence-based prevention: awareness-raising activities benefit from a dual approach that balances supply-chain security with a realistic understanding of consumer risks, leading to more effective public health alerts across the Union.

Arguments in support of recommendation 1.7

Proportionality in administrative oversight (Article 10): the mandatory appointment of a 'responsible officer' must be adapted to the operational reality of non-commercial entities. Structural rigidity in personnel requirements can inadvertently exclude smaller scientific actors from the legal framework.

2.29. Preventing administrative displacement: for smaller organisations, the flexibility to designate existing qualified staff ensures that limited budgets remain focused on scientific monitoring and public health rather than being diverted to unnecessary new executive hires.

2.30. Expertise-led security: internal staff, as primary field sensors, have the expertise to oversee compliance more effectively than external hires.

2.31. Maintaining operational continuity: internal designation ensures research continuity and uninterrupted monitoring of highly toxic substances.

2.32. Scaling requirements to risk: a tiered approach scales regulatory duties to precursor volume, preventing small labs from facing the same burden as large manufacturers.

Arguments in support of recommendation 1.8

A fragmented regulatory system across Member States hampers both illicit trade monitoring and scientific progress; a unified EU-wide framework is needed to support effective control and foster innovation.

2.33. Eliminating barriers to innovation: inconsistent national regulations act as a structural obstacle to development (R&D), as researchers face prohibitive administrative complexity when sourcing necessary substances across different jurisdictions.

2.34. Optimising cross-border tracking: unified regulatory language allows competent authorities to monitor substance trading with higher precision, closing the gaps created by 'regulatory arbitrage' where illicit actors exploit the weakest national links.

2.35. Standardising scientific sourcing: homogeneous rules ensure that laboratories, regardless of their location in the Union, have equitable and predictable access to the precursors needed for urgent pharmacological research.

2.36. Reducing administrative complexity: harmonisation reduces bureaucracy, allowing European researchers to focus on identifying new psychoactive substances instead of navigating multiple compliance rules.

Arguments in support of recommendation 1.9

Safeguarding scientific integrity and confidentiality (Article 28): the power of authorities to inspect and control must be balanced against the need to protect sensitive research environments. Invasive oversight can compromise the very scientific protocols designed to study the toxicity of new chemical variants.

2.37. Preventing 'protocol contamination': controls must be strictly risk-based to ensure that physical inspections do not disrupt the delicate integrity of ongoing chemical syntheses or longitudinal studies on substance mutations.

2.38. Confidentiality of emerging data: protecting researchers' protocols ensures sensitive data on new pseudo-legal mixtures is securely handled before publication.

2.39. Avoiding research deterrence: if oversight becomes disproportionately intrusive or unpredictable, researchers may avoid working with Category 3 precursors altogether, leaving a void in the scientific monitoring of highly dangerous substances like fentanyl analogs.

2.40. Targeted versus systematic oversight: by prioritising inspections based on objective diversion risks rather than routine administrative interference, the Regulation can maintain high security standards without hindering the autonomy of independent laboratories.

Arguments in support of recommendation 1.10

Evaluating long-term impact on therapeutic innovation (Article 41): the ten-year review must go beyond simple seizure statistics to assess the 'opportunity cost' of the regulation. A static evaluation risks ignoring the damage done to medical progress in the face of an ever-changing drug market.

2.41. Assessing the chilling effect: it is critical to measure whether the restrictions on Category 3 precursors have discouraged the pharmaceutical sector and independent labs from exploring new therapeutic molecules, particularly in the field of mental health and addiction treatment.

2.42. Evidence-based policy adjustment: given that the market has evolved towards highly toxic synthetic opioids, the review must determine whether the current regulatory framework has successfully promoted public health or whether it has inadvertently pushed production towards even more dangerous, unscheduled alternatives.

2.43. Stakeholder-driven evaluation: including researchers and medical practitioners in the review process ensures that the evaluation captures the real-world difficulties of conducting legitimate science under a restrictive regime, allowing for the correction of bureaucratic bottlenecks.

2.44. Monitoring the 'displacement' of research: the review should analyse whether scientific talent and investment have moved outside the Union to avoid the administrative burden of precursor control, potentially weakening Europe's ability to respond to future chemical threats.

3. PROPOSED AMENDMENTS TO THE LEGISLATIVE PROPOSAL OF THE EUROPEAN COMMISSION

Amendment 1

linked to recommendation 1.2

Text proposed by the European Commission	EESC amendment
Article 9	*Article 9*
Licence	**Licence**
8. The competent authorities may require operators to pay a fee for processing the application for a licence. Where a fee is levied, competent authorities shall adjust	8. The competent authorities may require operators to pay a fee for processing the application for a licence. ***Such fees shall be waived or significantly reduced for***

Text proposed by the European Commission	EESC amendment
the level of the fee set for small and medium-sized enterprises***. Such a fee shall be levied in a*** non-***discriminatory manner and shall*** not ***exceed the cost of processing the application***.	***universities, non-profit research institutes and philanthropic organisations, provided that the precursors are used exclusively for scientific or medical research and not for commercial purposes***. Where a fee is levied, competent authorities shall adjust the level of the fee set for small and medium-sized enterprises ***and for research entities, ensuring that such fees do*** not ***constitute a barrier to scientific innovation***.

Reason

To prevent administrative costs from discouraging independent research and small-scale innovation.

Amendment 2

linked to recommendation 1.1

Text proposed by the European Commission	EESC amendment
Article 25 **The Drug Precursors Information Repository** 4. The information referred to in paragraph 2, points (a) ***and*** (b) and the specific function referred to in paragraph 3 shall be publicly available and free of charge.	*Article 25* **The Drug Precursors Information Repository** 4. The information referred to in paragraph 2, points (a)***,*** (b***) and (c*) ***regarding trends*** and ***risks, as well as*** the specific function referred to in paragraph 3***,*** shall be publicly available and free of charge ***to ensure maximum transparency and informed public debate.***

Reason

Transparency is a safety tool. Access to data on risks and trends allows the scientific community to peer-review the evidence used for classification.

Amendment 3

linked to recommendation 1.6

Text proposed by the European Commission	EESC amendment
Article 26 **Training activities** 2. Member States shall organise, at least once a year, awareness-raising actions for operators ***making available on the market, importing, exporting, performing intermediary activities, possessing or using drug precursors***.	*Article 26* **Training activities** 2. Member States shall organise, at least once a year, awareness-raising actions for operators ***based on evidence and harm-reduction principles***.

Reason

To move away from a purely punitive narrative and toward a health-oriented and science-based understanding of substance use and trade.

Amendment 4

linked to recommendation 1.5

Text proposed by the European Commission	EESC amendment
Article 37 **Delegation of power**	*Article 37* **Delegation of power**
1. […] The Commission may add substances in Annex III ***either*** identified individually or in a generic way. ***When adding substances in a generic way***, ***the Commission shall clearly identify the group*** of ***substances and, if applicable, the individual substances which are to be*** exempted ***from the control and monitoring measures*** for ***scheduled drug precursors***.	1. […] The Commission may add substances in Annex III identified individually or***, only where strictly necessary and based on clear evidence of harm,*** in a generic way. ***In such cases***, ***an exhaustive list*** of exempted ***substances*** for ***legitimate research must be published simultaneously***.

Reason

To prevent 'legal grey zones' created by generic classifications that could lead to the pre-emptive abandonment of promising research projects and create risks because of unclear definition.

Amendment 5

linked to recommendation 1.10

Text proposed by the European Commission	EESC amendment
Article 41 **Review**	*Article 41* **Review**
[...] The report shall contain an assessment of how this Regulation is achieving its objectives.	[...] The report shall contain an assessment of how this Regulation is achieving its objectives ***and its impact on the availability of substances for legitimate scientific research and medical and general innovation***.

Reason

To ensure that the long-term evaluation of the law takes into account the potential 'chilling effect' on science, not just the success of law enforcement seizures.

Brussels, 29 April 2026.

The President
of the European Economic and Social Committee
Séamus BOLAND