VIEW PAPER

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Cefic Views on the revision of the EU Drug Precursor regulations

Cefic fully supports the need for EU legislation regulating the trade of drug precursors both within the EU and with non-EU countries. This support is in line with our industry's Responsible Care® commitment for safe, secure, responsible, and sustainable production and use of chemicals. We therefore stand by the European Commission's aim to ensure a high level of protection against illegal drug production and regulating the trade of substances that can be misused to manufacture illicit drugs by revising the Drug Precursor Regulations-

Chemical companies are highly engaged to prevent the misuse of their products, be it by actively cooperating with authorities when they receive suspicious requests, via the development and implementation of national and international guidelines, or by applying the "know your customer" principle. We are concerned by the misuse of chemicals to produce illegal drugs, in particular, by ways of manufacturing "designer precursors" or via online trade. We therefore agree on the need to address these policy challenges and are pleased to provide our views on how this can be done.

Our **top 6 recommendations** are:

1. Keep the regulations implementable and ensure legal clarity by continuing to schedule individual substances, clearly identifiable ideally by CAS numbers, rather than listing chemical groups/families based on their molecular structure.
2. Fully digitise all steps of the process for complying with the regulation.
3. Reduce confusion for economic operators and decrease administrative burden by ensuring an EU-wide harmonisation of the implementation between Member States, regulations, and with customs practices. This would particularly include a more harmonized approach to thresholds for scheduled substances in mixtures.
4. Ensure that potential bans on designer precursors (substances with no known legal current use) do not inhibit R&D activities. Ideally, operators with a licence for activities involving drug precursors would be excluded from the ban. Otherwise, we support the establishment of research license or notification mechanisms.
5. Effectively tackle illegal online trade, including by requiring licenses for private platforms wishing to trade sensitive substances.
6. Improve information provision for economic operators, including via e-learning tools and trainings.

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Policy recommendations

The future of scheduling: Effective and implementable

The proliferation of designer precursors requires modern and effective approaches that ensure a constructive collaboration of all relevant stakeholders. While we consider some of the policy options as effective ways forward, others are deeply concerning for us. In particular, we call for the Commission to continue scheduling substances on an individual level. Grouped/family scheduling can create legal uncertainty and exorbitant compliance costs for economic operators. In particular, clearly identifying which items produced or used by a company fall under the scope of the regulation would be technically unfeasible if scheduling is based on the chemical structure of substance group:

1. This would necessitate a complete and constant chemical analysis of all products handled by a company, a requirement that cannot realistically be implemented in the day-to-day operations. While chemical companies are currently highly engaged to ensure that drug precursors are handled in a responsible way, this would imply that they might no longer be technically able to ensure compliance with the regulation at all points with legal certainty.
2. Some enforcement and customs authorities may be confronted with considerable challenges if they were required to assess whether substances used in inspected products are part of a certain chemical group. We can already observe now that significant resource constraints inhibit the effective control of substances entering the European market, the need for a full chemical analysis of the molecular structure of incoming substances would aggravate this challenge. It needs to be ensured that the revised regulation is fully enforceable.
3. Grouped scheduling would create an unnecessary burden on both authorities and economic operators given that various substances without a relevant individual risk profile would need to be handled in the same way as drug precursors, simply based on the affiliation of both to the same group. Therefore, it is pivotal for us that the scheduling of substances remains to be done on an individual basis.
4. In this context, it is also important to ensure a continued alignment with the approaches taken in other trade control legislations, such as on F-Gases or explosive precursors. Creating divergences in this regard would create further legal uncertainty for economic operators, especially if the same substances are covered by different regulations.

As an alternative, we propose accelerating of the procedure to tackle new precursors. A shortening of the consultation periods would work for our sector, as long as it is ensured that sufficient time for the provision of adequate input remains. In particular, shorter periods could be implemented for new designer precursors which are usually not handled by economic operators. A digitisation of the system will facilitate the technical readiness of economic operators to respond to consultations more swiftly.

Moreover, alternative such as proactive and extended scheduling can offer a way forward with scheduling being based on individual substances and connected to unique identifiers.

We also generally agree with approaches introducing specific lists for designer precursors, comparable to the "Dutch Model"[1], to ban such substances with no known legal uses on the European level. Creating clarity, transparency and EU-wide harmonisation in this regard is needed. However, the focus needs to lie on private, not industrial users. A complete ban would inhibit the use of those substances for research

[1] As being referred to in the final report of the ad-hoc group on addressing designer-precursors in the EU.

and other emerging uses, creating potential fallouts on R&D activities of European industry. While ideally licensed operators would be excluded from any ban, granting research licenses in a simple and uncomplicated way, or permitting research on a notification-basis, can offer a way forward where this is not possible. When such activities lead to new, emerging uses, an efficient pathway to re-scheduling to the regular annexes needs to be created.

We further believe that the current category-based approach is a good way to adjust levels of necessary compliance activities and due diligence to the risk profile of substances. While certain scheduling reforms, additional categories or designer precursor lists (see above) could be required to better target current challenges, we call upon the Commission to avoid a departure from this well-established framework. A complete rehaul of the framework, ending the category-based system, would risk disrupting working due diligence, monitoring and compliance processes.

CAS is key

We emphasise the importance of authorities requesting CAS numbers prior to scheduling new substances, which is a very swift process, in order to enable the clear identification of substances by economic operators. This applies for potential new lists for designer precursors, as well as for regular scheduling. We can currently observe that the scheduling of IMDPAM without a CAS number makes it more difficult for companies to identify the substances in their management databases. Even if designer precursors do not yet have known legal uses, there are several reasons why CAS numbers are helpful for the implementation of any new regulatory regime for such substances:

1. Enable companies to quickly ensure that they do not use them via their established systems. CAS numbers are generally the only unique identifier for substances in those IT systems. This reduces administrative burden, increases clarity and decreases required consultation periods.
2. Facilitate the implementation of the regulation by (customs) authorities.
3. Ensure that companies, and research institutions can easily identify if a new substance they are working on in R&D activities falls under the regulation. Chemical companies are developing novel substances on a day-to-day basis and their trade compliance experts need to be able to quickly identify if such substances are affected by relevant regulations using company systems.
4. Enable the granting and control of research licenses. Such licenses required to continue activities involving designer precursors can only be effectively implemented if they are based on CAS numbers. The same would apply for a notification-based procedure
5. Allow for International standardisation. As CAS is an international system, requesting CAS numbers for designer precursors facilitates the international exchange and cooperation on such substances. Given the impact of the regulations on international flows, a link between customs regulations via the NC customs code is pivotal. This requires a precise designation of the precursor and is not compatible with a family or group of precursors.

If a scheduling of wider list of substances without CAS numbers is considered indispensable, lists banning their use exclusively for private users, not for industrial actors holding an operating license, would offer a way forward. Given that it is private users that engineer novel designer precursors for illicit purposes, we believe that this would represent an option to tackle the proliferation challenge without causing implementation problems, compliance costs, fallout on R&D activities and legal uncertainty for industrial operators.

Ensuring effective enforcement

We believe that an effective reform to improve enforcement needs to have a multidimensional base. Scheduling reforms mainly targeting industrial actors will increase administrative burden but may not have the desired effect of contributing to tackling illicit drug production by private operators. Therefore, it will be beneficial for reforms to consider other aspects, including online trade, adequate resource provision for authorities, information sharing and international partnerships in order to reach the intended impact. In particular, we suggest the following steps:

1. Providing competent authorities with the necessary analytical methods, equipment and capacities, in particular, laboratory equipment, to analyse substances. This would allow them to better identify e.g. new designer drug precursors and fake labels. Moreover, improved customs risk assessment capacities can play a crucial role, as illustrated by the recent achievements of Belgian authorities in seizing illicit drug precursor shipments by using the EU's new Import Control System ICS2[2]. Effective enforcement can only be ensured if all relevant authorities are able to rely on the latest technology.
2. Improving notification mechanism and monitoring for suspicious transactions. We suggest to set up a mechanism by which authorities would share information about relevant suspicious transactions with licensed industrial operators to enable them to adapt their monitoring and due diligence activities accordingly. This can happen in the context of broader initiatives to improve intelligence sharing and cooperation between governments and industry (as well as intergovernmental). Additionally, we call for the development of a platform which makes it possible to submit suspicious requests and websites/suppliers, for example integrated into a new Drug Precursor IT solution. Follow-up information related to such reporting would further help to emphasize the importance of such reporting to all stakeholders.
3. Partnerships with third countries. Such cooperations, in particular, with China and India, need to be stepped up, to prevent imports from non-EU manufacturers from being a source of illicitly used drug precursors. Required timeframe between arrival of shipments at the port of origin and shipment provide a window for customs inspections of suspicious deliveries, which is a reason why investigation at the country of origin can often be more effective. The development of information exchange capacities is required in order to improve the possibilities of authorities to detect and monitor suspicious transactions. This can contribute to the important work of identifying high risk ports. In the past, the European chemical industry was involved in information and cooperation missions to third countries (China, the Middle East, etc.) to present public-private partnerships on precursors in force in Member States, and tools developed together. EU private sector should continue to be involved in these missions, considering that the private sector from third countries is also invited.

Tackling illegal online trade

We see online trade of drug precursors on private online platforms as a particular challenge. While closed B2B market places (including B2B corporate webshops) present a controlled environment where producers check credibility, bank accounts, end-use-declarations etc., it is not always ensured that open private platform operators assume responsibility for the usage of the substances they sell. An effective framework regarding private online platforms and social media websites is needed to ensure that

[2] https://x.com/EU_Taxud/status/1778433133043421390

platform operators bear the legal responsibility for trade happening via their websites, existing loopholes need to be closed to ensure that the same rules that apply offline also fully apply online. The explosive precursors regulation or the CLP Regulation offer examples on provisions to better control online trade. We support policy coherence with such policies, as well as with the Digital Services Act (DSA).

While the DSA can improve the enforcement framework for noncompliant online content, it needs to rely on robust sectoral legislation defining obligations for operators and illegality of transactions. We suggest introducing specific regulations and enforcement activities for private platform operators wishing to allow the trade of drug precursors, including those listed in the voluntary monitoring list[3], on open websites. Such operators would need to acquire "trusted trader" licenses, combined with a list of relevant obligations to mirror the due diligence conducted by industrial operators. We propose that this includes obligations to ban accounts from which suspicious transactions were conducted and providing for a mandatory verification of the license of a buyer in the interface of the website. Such an interface should ensure that the purchase cannot be conducted by actors that do not fulfill the requirements. Access to the database of licensed operators for companies can also help in this regard.

In addition, where the DSA does not apply, drug precursor specific legislation needs to prevent loopholes. One area are social media marketplaces, for which different requirements as for regular online market places (e.g. tracing sellers) apply. Given that industrial operators do not acquire their inputs on social media platforms, the trade of substances that are not intended for private use on such platforms should not be possible. Furthermore, certain obligations, e.g. on compliant platform design, do not apply for small- and micro-platforms. In contrast, it is often exactly such small platforms, sometimes operated by individuals, where drug precursors are proliferated into an illicit way. Requiring licenses for online sales of drug precursors could render the sale of drug precursors by criminal actors via purpose-built platforms illegal and provide the adequate framework for an implementation via the DSA. Apart from improving the legal framework, effective enforcement[4] by public authorities is key for stopping illegal online trade of drug precursors.

In short, we believe that sensitive substances, such as direct precursors, should only be traded via stable marketplaces, e.g. industry-to-industry. We suggest in this context to study how a level playing field for all market participants can be ensured aiming to target enforcement activities especially on those actors with highest risks, such as e-commerce, while reducing wherever possible the administrative burden for compliant low-risk actors. It should be noted that, industry due diligence already plays an important role to reduce misuse of drug precursors. The "know your customer" principle is one of the key tools to prevent the misuse and diversion of products. Its implementation is a common practice by economic operators. Relevant substances are sold only to known business to prevent illicit actors from acquiring them. Examples where this principle is outlined are the VCI (German association of the chemical industry) voluntary guidelines stating that non-scheduled substances should only be sold to known, reliable and trustworthy customers, the French sensibilization brochure on monitoring drug precursors, which were developed in cooperation with France Chimie, or the ICCA voluntary stewardship practices on BDO & GBL.

[3] An alternative for the direct inclusion of substances from the voluntary monitoring list in the obligations for online trade could be to create a specific category within the Drug Precursor framework for substances that have a relevant potential of misuse and direct narcotic properties but where a scheduling as Category I is not feasible for practical reasons (e.g. use at construction sites which cannot be audited sites in the case of GBL).

[4] In this context, we would reiterate the important messages lined out in the Report of the High-Level Roundtable on the Chemicals Strategy for Sustainability.

Furthermore, we see the need for additional studies and investigations to obtain quantitative insights into main channels and origins for illicitly traded drug precursors. Web research shows the ease with which web-shops trading sensitive substances, that should not be sold to private users, can be found. Furthermore, the known problem of non-compliant third country import exists, EMCDDA's European Drug Report 2024, for example, states that "Drug precursors and related chemicals are also often reported to be sourced from China". Insights from national authorities that we received via member associations show that few specific third countries are the main source of chemicals being abused as drug precursors in Europe.

Making the regulation fit for the 21st century.

We consider a full digitisation of the implementation of the regulation by economic operators a key priority. The current paper-based system is cumbersome and creates unnecessary burden for economic operators. Digitisation will significantly reduce related administrative costs for companies, which is particularly relevant for SMEs, while simultaneously improving effective enforcement: It enables shortened consultation periods and prevents fraud using forged documents. We propose the following key features for a digital system to implement the drug precursor regulations:

1. Digitisation of the complete process. An efficient digital solution will allow to create and extend import/export license, permits, registration requests, and end use declaration electronically, as it is already the case in some Member States for certain elements. Permits should subsequently be granted via the same platform in a downloadable format. We suggest basing the system on cloud technology. Furthermore, we call for the introduction of digitised authentication procedures and a Union-wide acceptance of reliable digital signatures. The latter was possible in certain Member States while restrictions related to the Covid 19 pandemic were in places but was often reverted afterwards, even though it simplifies the process for economic operators.
2. A user-friendly digital portal. We recommend that the new digital platform has several key features facilitating the effective implementation of the regulations by companies: a) Providing template forms for all relevant processes; b) Automatically checking data for completeness and correctness; c) Offering the possibility to attach documents; d) Allowing to check customer End Use Declarations; e) Featuring a permitting dashboard which authorities can use to validate requests and where companies can check the processing status; The same dashboard should enable direct communication e.g. on follow-up questions and additionally required information.
3. Database of registered operators. It would be beneficial to grant economic operators access to the already existing EU database on licensed operators to reduce the need to acquire certifications for each transaction (or to create new databases with such functionalities). In addition to reducing administrative burden for companies, this would also effectively prevent illicit actors from trying to acquire drug precursors using fake licences. Currently, companies do not have access to the EU database on licenced operators and therefore need to individually request licenses from business partners even though this information is available on the European level.
4. Harmonised systems. We propose that the digital system will be harmonised for all Member States. A necessary prerequisite is a harmonised application of the regulations across the EU. The tools should further be aligned to the approach taken for other trade control regulations, where possible.
5. Digitised verification. We support an integration of the licences/authorisations (i.e. their ID-number) in the customs declaration and allowing for an online verification similar to systems which already exist in the area of rules of origin. We further ask to enable the use of QR

codes/scannable labels as an alternative to paper based documents enabling customs agents to check the required documentation during the shipment of drug precursors.

6. Interoperability between electronic systems. We call for making full use of the benefits of the Single Window Regulation 2022/23 for the implementation of the Drug Precursor regulation. Furthermore, we ask for enabling the communication between the new electronic platform for Drug Precursors and company as well as customs systems via API integration. Creating connections to (national) customs systems, and in the future the new datahub in the context of the Union Customs Code (UCC) reform, could remove the need for economic operators to do complete and separate annual reporting: Using the data submitted to customs over the year for this purpose would enable them to fulfil reporting requirements by simply confirming the report that was build up during the separate submissions of data. This connects to the more general need of future proofing the implementation of the regulation by ensuring UCC compatibility.
7. Automated processes. A further simplification of the process could be archived by introducing automated process. We suggest evaluating the feasibility of such approaches for example for requests to selected third countries and respective permitting.
8. Stakeholder inclusiveness. Given the comprehensive experience that experts at company level have in implementing the regulations, we call for the process for the development of the IT system to include a consultation and collection of input from economic operators.

Reducing unnecessary complexities

The current revision offers the opportunity to reduce misalignments, complexity and duplications of requirements to further decrease administrative costs for economic operators.

We fully support the idea to merge/align the two regulations. This will reduce confusion created by misalignment and increase clarity, in particular for SMEs. However, the merger should not lead to an implementation of stricter clauses on external trade to the intra-EU trade as levels of risks differ.

Currently, pre-export authorisations are additionally required in cases where import authorisations have already been provided during the application for an export authorisation. It should be considered if this can be seen as a duplication of requirements, unnecessarily delaying the administrative process.

We further propose that simplified procedures for repeated transaction that are currently possible for category 3 substances are extended to category 2 substances. Frequent sales between the same known legitimate industrial operators constitute a low-risk activity for which compliance costs should be reduced.

Moreover, we ask to align the regulations with general customs procedures in the best possible way aiming to avoid unnecessary requirements or duplication. This also includes ensuring that definitions are consistent and that conflicting rules are avoided. Currently, misalignments between possible customs procedures, such as the single authorisation for simplified procedures, and the implementation of the regulations on drug precursors exist. In particular, some national authorities require responsible officers for drug precursors to be either nationals or registered with an address in the country where the export authorisation is sought. This is in direct contradiction to the purpose of the single authorisation, which allows economic operators to apply centrally to the national competent authority for exports in an EU Member State. Responsible officers need to be familiar with local operations and the specific substances exported from a facility, which is why they cannot be employees resident in the country where the permit is applied for single operations if the export takes place in another country.

Proliferation is a European challenge

We see the need for an increased harmonisation of legal requirements, implementation practices and guidelines at EU level. The adequate handling of drug precursors is a joint European issue. Where one European legislation exists, the aim should be one European approach to interpreting and implementing it. Different options to attain this should be explored, including via the EMCDDA (soon to become the EU Drugs Agency), or a potential additional European umbrella agency that collects information, communicates alerts, establishes common procedures & guidelines etc. This should progressively lead to establish a common approach towards internal as well as external trade in listed substances, including a fully harmonised voluntary listing.

In particular, the heterogeneous implementation of the definition of mixtures by national authorities poses problems, especially for companies operating transnationally. It is also a matter of the internal market. We therefore support the consideration of EU-wide minimum thresholds for scheduled substances in mixtures. It would increase clarity for economic operators and simplify the enforcement by authorities, by reducing the need for them to engage resources in the control of substances that are not relevant for criminal purposes. Especially SMEs would benefit from this form of increased guidance. We propose realising the improved harmonisation either by (1) setting EU-wide fixed thresholds per category based on current experience, or by (2) establishing a new EU expert body that can advise on particular thresholds for specific mixtures/products. Any thresholds need to be realistic and practical: they need to serve the purpose of preventing illegal drug trafficking while not adding disproportionate administrative burden on companies. In line with the current practices, mixture containing a share of a scheduled substance above the threshold can still fall outside the scope of the regulations based on the extractability and economic viability of the extraction. The corresponding assessments should continue to be conducted by undertakings themselves. We believe that the current definition of extractability and economic viability is fit for purpose and needs to be kept flexible. Additional technical criteria would complicate, rather than facilitate, the implementation of the regulations.

Improving information access for the private sector

While chemical companies are highly engaged to ensure that their products are handled in a responsible way and cannot be misused by illicit actors, lack of adequate information can sometimes reduce the effectiveness of their efforts. This particularly applies to SMEs with a lack of resources for specialised staff. For example, some companies are currently not receiving the voluntary monitoring list even though there are engaged in the trade of relevant substances. That both impedes the implementation of respective due diligence measures and creates confusion regarding requests received by business partners.

In this context, we see the need for improved awareness-raising and information provision for economic operators. In particular, the current e-learning tool needs to be updated and supplemented by additional tools, such as awareness brochures for the general public. By consulting the private sector on the further development of the tools, concerns of affected companies can be incorporated, as was done during the elaboration of the first version of the tool, to which Cefic contributed. Regulatory communication needs to be modernised to facilitate the adequate dissemination of relevant information to stakeholders.

Training requirements are an additional effective tool to improve awareness and the correct orientation of all actors in the value chain. We call for trainings to be offered to economic operators on a regular basis and to be provided by authorities themselves.

Conclusion

Overall, we welcome the opportunity to modernise the regulations and their implementation and reduce the burden faced by companies by means of digitisation, harmonisation and alignment. Such reforms offer an important opportunity to significantly reduce the related administrative costs for the EU industry. Regarding the different options to better control designer precursors, practical implementability of any possible solution is crucial and it needs to be ensured that all revisions are compatible with the operations of licit companies and do not cause disproportionate administrative costs or legal uncertainty. It is critical to find tools to effectively target illicit actors without creating excessive burden for lawful and responsible operators. We stand by to collaborate in the development of effective and efficient policy solutions and appreciate any opportunity to strengthen public-private cooperation on this important issue.

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About Cefic
Cefic, the European Chemical Industry Council, is the forum of large, medium and small chemical companies across Europe, accounting for 1.2 million jobs and 14% of world chemicals production. On behalf of its members, Cefic's experts share industry insights and trends, and offer views and input to the EU agenda. Cefic also provides members with services, like guidance and trainings on regulatory and technical matters, while also contributing to the advancement of scientific knowledge.