EUROPEAN COMMISSION

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REGULATORY SCRUTINY BOARD OPINION

Proposal for a Regulation of the European Parliament and of the Council on the European Union Drugs Agency

{COM (2022) 130 final}
{SWD(2022) 8 final}
{SWD(2022) 9 final }

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB

Opinion

Title: Impact assessment / Proposal to revise the mandate of the European Monitoring Centre for Drugs and Drug Addiction

Overall 2nd opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

Since 1993, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) has provided the EU and its Member States with information on drugs and drug addiction and their consequences. The Agency's core tasks are to collect and analyse data, improve data comparison methods and disseminate data. It cooperates with European and international organisations as well as with third countries.

The drug phenomenon has evolved considerably since the founding of the Agency. The drug problems have become more complex and pervasive. They now represent an integral element of many of the health and security issues that European countries face today.

The present initiative is an element of the new EU Security Union Strategy.

(B) Summary of findings

The Board notes that the report now better explains the context and the current mandate of the Drugs Agency.

However, the report still contains significant shortcomings. The Board gives a positive opinion with reservations because it expects the DG to rectify the following aspects:

(1) The problem analysis does not sufficiently distinguish between the shortcomings of the Regulation and new challenges that may require a revision.

(2) The intervention logic is not clearly set out.

(3) The presentation of policy options is confusing and does not bring out clearly the available policy choices.

(4) The report does not show the costs and benefits of individual options. It is unclear on how the preferred option aligns with the EU budget framework, and what the corresponding ambition level would be.

This opinion concerns a draft impact assessment which may differ from the final version.

Commission européenne, B-1049 Bruxelles - Belgium. Office: BERL 08/010. E-mail: regulatory-scrutiny-board@ec.europa.eu

(C) What to improve

(1) The report should base the problem description more on the evaluation findings. It should distinguish between the shortcomings of the current Regulation and new challenges that may require a revision. It should also better differentiate between findings of the evaluation and other evidence gathered (e.g. through stakeholder consultations) that might change the evaluation's conclusions. The problem analysis should explain the current restrictions in the Agency's mandate relating to other substance-based addictions and poly-drugs. It should discuss to what extent resource constraints have prevented extending the Agency's activities. It should also clarify the relationship and interaction with other data collection instances and European bodies to address potential overlaps. The problems 'insufficient support to Member States' and 'the need to develop EU-level prevention and awareness raising campaigns' should be substantiated with more robust evidence and critically assessed from a subsidiarity and EU added-value perspective.

(2) Based on a more coherent narrative, the report should present a clearer intervention logic. It should convincingly demonstrate how the options (and the measures contained therein) would deliver on the specific objectives and ultimately tackle the identified problem drivers. A clear visual presentation of the intervention logic should be included in the main text. Specific objectives should be expressed in more SMART terms, so that progress can be measured.

(3) The presentation of the policy options remains complex, confusing and geared towards the preferred option. On the one hand, some of the key options (e.g. scope of action, priority activity areas, new tasks) seem artificial and not really presenting alternatives. On the other hand, certain available choices (e.g. on scope, laboratory capacities, national focal points) are not clearly identified or sufficiently explained upfront. The report should therefore be revised to present genuine alternative options, possibly with different ambition levels (e.g. minimum, targeted or maximum revision), that could tackle either simultaneously all the identified problems (in case these are inter-related) or by key problem area (in case these are independent). Following such a logic, the preferred option should be one of the options.

(4) The report should compare all options in terms of effectiveness, coherence and efficiency. This should allow to provide greater clarity on the (budgetary) costs and benefits of the alternative options, including those resulting from different implementation choices (e.g. expanding or merging the agency). In this context, it seems premature to discard a merger with another agency upfront, given the potential cost savings and overall budgetary constraints.

(5) The report should clarify how the preferred option is aligned with the EU multiannual financial framework 2021-2027 and be clear on what ambition level will be possible within this frame. It should further assess the potential of a charging fees option, by at least giving broad indications on potential costs and benefits and potential impact on the overall budget for this initiative.

(6) The report should further develop the REFIT dimension by giving special consideration to simplification and burden reduction potential, quantifying it as far as possible.

(7) The report should be further streamlined in order to have a more synthetic and focused presentation, bringing out a more convincing narrative. Relevant information should be

presented where it belongs (e.g. description of options in the option section and not in the impact analysis). Annex 1 should provide a complete table indicating how all the suggestions of the Regulatory Scrutiny Board have been taken into account, including 'Box C – what to improve'.

The Board notes the estimated costs and benefits of the preferred option in this initiative, as summarised in the attached quantification tables.

(D) Conclusion

The DG may proceed with the initiative.

The DG must take these recommendations into account before launching the interservice consultation.

If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.

Full title	Impact Assessment on a proposal to revise the mandate of the European Monitoring Centre for Drugs and Drug Addiction
Reference number	PLAN/2019/5417
Submitted to RSB on	14 April 2021
Date of RSB meeting	Written procedure

ANNEX: Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct and indirect benefits		
Better understanding of the drugs phenomenon in Europe	N/A	Updating the Agency mandate to equip it with the necessary means to deal with the current and future challenges posed by drugs in the EU would lead to a better understanding of the drugs phenomenon. If better information were available, it would be easier for the European and national level to react to developments. It would also be easier to do so in a coordinated manner across borders, which is crucial as the drugs phenomenon was and increasingly is of cross-border nature. It would allow addressing new developments on the markets and in the health area. Ultimately, the strengthened actions of the Agency would contribute to the health and security dimension of EU drugs policy.
Savings in administrative costs in the Member States	N/A	The streamlining of reporting obligations would lead to a reduction of administrative costs in the Member States, at least in the mid- to long-term. This has to be seen alongside the necessary increase of the EU contribution to the Agency. Unfortunately, due to a lack of data, no quantified data is available on the possible savings in the Member States.
Drug supply and demand reduction	N/A	The ultimate goal of any revision of the Agency would be the contribution of its work to drug supply and demand reduction. The Agency cannot do this on its own, but the information it makes available leads to a better understanding of the drug phenomenon and availability of better intelligence. This is the evidence-base for EU drugs policy, which has as its strategic goals the disruption of drug markets, prevention and awareness raising, and addressing drug-related harms.

II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent[1]
Option 3	Direct costs	N/A	N/A	N/A	N/A	Some IT-investments might be needed to extend the current data collection and monitoring system to other substances. However, these should not be major in view of the system already being in place and are integrated in the cost estimates of the recurrent costs.	*EU budget:* Approx. EUR 1.5 million/year (without drug precursors); with drug precursor monitoring, this would increase to about EUR 2.5 million/year (only in the final years of the MFF) → Overall impact on MFF 2021-2027: EUR 6-11 million *National budgets:* There might be some minor cost increases for Member States in case data for the substance-based addictions is not yet collected in the way needed. However, in the mid- to long-term the streamlining of reporting obligations will

[1] The recurrent costs include staff costs.

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							reduce these costs.
	Indirect costs	N/A	N/A	N/A	N/A	– – –	– – –
Option 4 (monitoring, threat assessment and support to Member States; national focal points) + **Option 5** (all new tasks except for the international dimension)	Direct costs	N/A	N/A	N/A	N/A	See above Option 3A.	*EU budget:* Approx. EUR 4.5-5.5 million/year → Overall impact on MFF 2021-2027: EUR 18-22 million If the co-financing of the national focal points would have to be increased, this would have an impact of up to EUR 2 million/year → Overall impact on MFF 2021-2027: EUR 7-9 million *National budgets:* No costs to be expected for the monitoring, threat assessments and support to Member States. However, strengthening the role of the national focal points will lead to an increase in their resource needs. It is up to the Member States on how much (additional) funds they will make available for the national focal points; therefore, the overall impact on national

							budgets cannot be calculated.
	Indirect costs	N/A	N/A	N/A	N/A	– – –	– – –
Option 4 (virtual laboratory)	Direct costs	N/A	N/A	N/A	N/A	As no physical laboratory is set up under the preferred option, no particular initial costs are needed, except for some possible IT investment.	*EU budget:* Approx. EUR 4-5 million/year annual running costs; the staff ramp up will be longer than for the other tasks to ensure smooth budget absorption. → Overall impact on MFF 2021-2027: EUR 16-20 million *National budgets:* No costs to be expected
	Indirect costs	N/A	N/A	N/A	N/A	– – –	– – –
Option 5 (international dimension)	Direct costs	N/A	N/A	N/A	N/A	No set-up costs to be expected.	*EU budget:* Approx. 1.5 million/year → Overall impact on MFF 2021-2027: EUR 4-6 million
	Indirect costs	N/A	N/A	N/A	N/A	– – –	– – –

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Opinion

Title: Impact assessment / Proposal to revise the mandate of the European Monitoring Centre for Drugs and Drug Addiction

Overall opinion: NEGATIVE

(A) Policy context

Since 1993, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) has provided the EU and its Member States with information on drugs and drug addiction and their consequences. The Agency's core tasks are to collect and analyse data, improve data comparison methods and disseminate data. It cooperates with European and international organisations as well as with third countries.

The drug phenomenon has evolved considerably since the founding of the Agency. The drug problems have become more complex and pervasive. They now represent an integral element of many of the health and security issues that European countries face today.

The present initiative is an element of the new EU Security Union Strategy.

(B) Summary of findings

The Board notes the additional information provided in advance of the meeting.

However, the Board gives a negative opinion, because the report contains the following significant shortcomings:

(1) The report does not clearly demonstrate the problems that this initiative aims to tackle. It does not sufficiently differentiate between shortcomings of the current regulation and new drug challenges, for which the Agency could be part of the policy response. It does not provide an overall convincing and clear narrative that is coherent with the results of the preceding evaluation.

(2) The presentation of policy options is overly complex and not sufficiently linked to the choices that policy makers should consider.

(3) The report insufficiently assesses the added value and proportionality of some of the proposed measures. It is not specific enough about the options' simplification and cost reduction potential.

This opinion concerns a draft impact assessment which may differ from the final version.

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(C) What to improve

(1) The context section should better present the current mandate of the Agency. It should briefly explain its monitoring and data collection tasks, and their intended role in supporting EU and national anti-drugs policies.

(2) Given the largely positive findings of the preceding evaluation, the report should be clearer on the evidence-base of the problem analysis. It should specify which problems stem from shortcomings of the current Regulation and which are the new issues that have emerged, for which new action by the Agency could be an element of the policy response. The problem analysis should clearly motivate the type and scale of agency changes that the options suggest. In doing so, the report should differentiate more clearly between the overall development of drugs challenges and the contribution the Agency could realistically make in tackling those.

(3) The report should better explain the added value of the Agency compared to other data collection instances and bodies (national, EU and international). It should substantiate the need for extending the Agency's current mandate to develop threat assessment capacities, indicating the operational testing shortcomings across the EU. It should better argue the EU-added value of providing support to Member States. It should also substantiate the benefits of EU-level drug communication as compared to more targeted communication at Member State, regional or local level.

(4) The report should simplify the presentation of options and better link them to the main policy choices that policy makers should consider. It should present genuine alternatives for each of the key issues and assess and compare them more systematically. It should consider other combinations of (sub-) options under the preferred policy package, possibly differing in terms of ambition level, scope of action or budgetary implications.

(5) The report should further develop the REFIT dimension and the scope for simplification and cost reduction under the various options. As far as possible, it should provide quantitative estimates of foreseen cost reductions from centralising tasks (data collection, testing capacity, communication, etc.). It should specify for each task why the Agency would be more efficient in carrying it out than the Member States.

(6) The report should present a clearer and more convincing narrative. It should be shortened by avoiding repetitions and better focusing on the relevant information in the problem definition, options and impact sections.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion

The DG must revise the report in accordance with the Board's findings and resubmit it for a final RSB opinion.

Full title	Impact Assessment on a proposal to revise the mandate of the European Monitoring Centre for Drugs and Drug Addiction
Reference number	PLAN/2019/5417
Submitted to RSB on	18 November 2020
Date of RSB meeting	16 December 2020