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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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Delegations will find attached document SEC(2025) 304 final.

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EUROPEAN COMMISSION

Brussels, 15.11.2024
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REGULATORY SCRUTINY BOARD OPINION

**REPORT FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND
SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS
on the interim evaluation of the EU4Health Programme 2021-2024**

{COM(2025) 709 final}
{SWD(2025) 369 final}



EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
Ares(2024)

Opinion

**Title: Evaluation / Interim evaluation of the EU4Health Programme
2021-2027**

Overall opinion: NEGATIVE

(A) Policy context

Regulation (EU) 2021/522, adopted in March 2021, established the EUR 5.7 billion EU4Health Programme (2021-2027). It has four general objectives: (i) to improve and foster health in the Union; (ii) to protect people from serious cross-border threats to health; (iii) to improve access to medicinal products, medical devices and crisis-relevant products; and (iv) to strengthen health systems.

The interim evaluation aims to measure the Programme's progress up to April 2024, across the 27 Member States and the six non-EU countries associated.

(B) Key issues

The Board notes the additional information provided and commitments to make changes to the report.

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

- (1) The intervention logic is not clear on the causality between investment, outputs, results and impacts. The monitoring system and available indicators are not sufficiently analysed to support the evaluation and to identify areas for their improvement.**
- (2) The report makes statements not supported by evidence and analysis. The report is not clear about the additionality of the Programme. The effectiveness analysis is incomplete. The approach to assessing efficiency is conceptually incorrect. The potential for simplification and administrative cost reduction is not sufficiently assessed.**
- (3) The conclusions do not fully reflect the key findings of the analysis. The lessons learned are not sufficiently developed to improve the implementation of the Programme and to allow for final evaluation.**

This opinion concerns a draft evaluation/fitness check which may differ from the final version.

(C) What to improve

(1) The explanation of the intervention logic should be further developed to identify the causal link between inputs, actions, outputs, results and impacts. The causal link should be clear and specific for all areas of intervention in view of its importance for the entire assessment. If the causality cannot be established, the report should explain how it accounts for the absence of causality, be clear throughout whether the analysis refers to causal relationships or not and explicitly state limitations. As this is the interim evaluation the report should draw lessons regarding methodology and data collection to overcome causality limitations so that the impact of the Programme can be assessed in the final evaluation.

(2) The report should explain how the specific objectives could be further operationalised in terms of their specificity and measurability to allow evaluation and measurement of the performance of the intervention.

(3) The report should further analyse the available indicators from the existing monitoring system, including the Programme Performance Monitoring and Evaluation Framework (PPMEF), and reflect on their usefulness for this evaluation as well as for a final evaluation. In this respect, it should critically assess the findings of support study.

(4) Given that at present, some indicators cover areas with multiple investment and policy activities, in particular at national level, and that there is only one impact indicator, the report should reflect on how the results would be measured, the causal links established, and impacts assessed and appropriated to the Programme in the final evaluation. It should explore what data and indicators may be needed to provide robust and meaningful input to assess the results and impacts of the Programme. In this context, the report should elaborate on how an improved and revised methodology and PPMEF would address those issues.

(5) The report should clearly establish the appropriate points of comparison. It should attempt to create a chart or a table illustrating the baseline (i.e. the pre-Programme situation in 2020), the expected achievements (i.e. what was expected at time of adoption to be achieved by 2024), and the actual situation in 2024. In terms of inputs, the report should present a reflection of the consequences of the reduction of the Programme budget. It should include a description on how the Programme operates, how much money has been spent, and who are the beneficiaries. In terms of completeness of the analysis, the assessment should be performed on all programs and activities under each strand.

(6) The report should provide more explicit analysis of the additionality of the Programme. In this context, the report should isolate the effects of the Programme from possible effects due to other interventions or draw conclusions where it is not possible due to PPMEF limitations. The EU added value and relevance analysis should be further strengthened and focused on the added value that goes beyond what could reasonable be achieved from Member States acting independently and considering the size of the Programme.

(7) The report should better explain the limitations of the effectiveness analysis. It should clarify whether the analysis at the level of outputs is complete, i.e. whether it covers all actions and activities, or is based on selection of those. It should identify and present shortcomings or underperforming elements in the intervention, if any. The flow of analysis-conclusions is not always evident, and the report often makes statements without clear support from the preceding analysis. Statements, not supported by the analysis or the available evidence, should be avoided. The report should not imply causality between the intervention and the observed effects unless supported by the analysis of available data. The

conclusions from the effectiveness assessment should clearly follow from the analysis and the available evidence.

(8) Given that the estimates of Return on Investment (ROI) included in the report neither present the actual ROI of the Programme, nor are specific to the Programme, these estimates should not be used in the efficiency analysis and in the related conclusions. The report should clearly explain the limitations of the efficiency analysis at this stage of the implementation of the Programme. It should be clear upfront and consistent throughout that the analysis is based on the outputs and to the limited extent on the results, not the impacts. Any conclusions on efficiency of the Programme should be adjusted to reflect the underlying analysis and limited available evidence. The report should further assess the potential for simplification and reduction of administrative burden. In this context, it should better use the findings from the customer journey case studies. It should compare the administrative costs related to the implementation of the Programme with the administrative costs of implementing other programmes.

(9) The Cost/Benefit Table should be amended to include all relevant costs, both investments and administrative costs, as well as benefits to the extent possible, and to remove any inconsistencies with the proceeding analysis. The Table on Potential Simplification and Burden Reduction should be further developed once the analysis mentioned above is completed.

(10) The conclusions and lessons learned should be revised to better reflect the analysis and better inform for future action in particular on improving the implementation and the monitoring of the Programme. The conclusions should be objective, clearly supported by the analysis and the available evidence, and taking into account all identified potential underperforming elements. The conclusions should summarise the findings of the assessments for all evaluation criteria. Lessons learned should make better use of conclusions from the support study to inform on future actions. They should be further elaborated to focus on improving the implementation of the Programme and should reflect on necessary methods and data for the final evaluation.

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

(D) Conclusion

The lead Service must revise the report before launching the interservice consultation.

The lead Service may resubmit to the Board a revised version of this report.

Full title	Interim evaluation of the EU4Health Programme 2021-2027
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