**European Parliament**
2019-2024

*Committee on Budgets*
*The Chair*

23.2.2024

Mr Pascal Canfin
Chair
Committee on the Environment, Public Health and Food Safety
BRUSSELS

Subject: Opinion on Opinion on the Commission proposal on a Regulation of the European Parliament and of the Council on for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency COM(2023)0193; (2023/0131(COD)).

Dear Mr Chair,

Under the procedure referred to above, the Committee on Budgets' Coordinators decided at their meeting of 23 May 2023 to adopt an opinion in the form of a letter. The committee adopted the opinion at its meeting[1] on 14/02/2024 and mandated me to convey the position set out below.

**Background to the proposal**

The general objective of the proposal is to guarantee a high level of public health by ensuring the quality, safety and efficacy of medicines for EU patients and harmonise the internal market and more specifically to:

1. Promote innovation, in particular for unmet medical needs, including for rare disease patients and children.

2. Create a balanced system for pharmaceuticals in the EU that promotes affordability for

[1] The following were present for the final vote: Johan Van Overtveldt (Chair), Anna-Michelle Asimakopoulou, José Manuel Fernandes, Michael Gahler, Niclas Herbst, Monika Hohlmeier, Janusz Lewandowski, Siegfried Mureşan, Eleni Stavrou, Angelika Winzig (for EPP), Jonás Fernández, Eider Gardiazabal Rubial, Eero Heinäluoma, Camilla Laureti, Thijs Reuten, Pedro Silva Pereira, Nils Ušakovs (for S&D), Olivier Chastel, Katalin Cseh, Vlad Gheorghe, Moritz Körner, Eva Maria Poptcheva, Nils Torvalds (for Renew), Rasmus Andresen, Alexandra Geese (for Greens/EFA), Bogdan Rzońca, Grzegorz Tobiszowski, Roberts Zīle (for ECR), Joachim Kuhs, Maria Veronica Rossi (for ID) Andor Deli, Hervé Juvin, Lefteris Nikolaou-Alavanos (for NI)

health systems while rewarding innovation.

3. Ensure access to innovative and established medicines for patients, with special attention to enhancing security of the supply across the EU.

4. Reduce the environmental impact of the pharmaceutical product life cycle.

5. Reduce the regulatory burden and provide a flexible regulatory framework.

According to the legislative financial statement accompanying the Proposal on a Regulation of the European Parliament and of the Council on for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, the budgetary implications are mainly related to additional tasks to be carried out by the European Medicines Agency in terms of providing scientific, administrative and IT support in the following main areas:

- enhanced pre-authorisation scientific and regulatory support;
- decision-making on orphan designations and management of the Union Register of designated orphan medicinal products;
- active substance master file assessment and certification;
- inspection capacities for inspections in third countries and support to Member States;
- environmental risk assessment strengthening;
- shortage management and security of supply.

The proposal foresees that most of the foreseen additional tasks of EMA will be carried out by 54 additional Temporary Agents funded by fees while other 6 additional Temporary Agents and the costs for the incentives to “not-for-profit” entities will be financed through an increase of the appropriations from the EU budget in the years 2026 and 2027 by 4.4 million EUR and an internal redeployment within heading 2b, i.e. by an equal reduction of EU4Health programme. According to the information provided by the Commission at different budgetary trilogues, this constitutes the second reinforcement of EMA since the start of the MFF and the third reduction of the EU4Health programme since the start of the MFF.

**Position of the Committee on Budgets**

The BUDG committee is of the general opinion that entrusting new tasks to decentralised agencies should be financed from fresh resources and should not lead to reduce other equally important priorities to be implemented in other programmes even if in the same policy area, in this case Health. Thus, redeployments from the EU4Health programme should be limited and examined with due care. Furthermore, the overall proposed increase in temporary agents is significant (around 7% above the level agreed in the 2024 budget) which deserves special attention as no full coverage by fees as planned would significantly further impact the Union budget.
In this context, we deem useful to provide the ENVI Committee with technical support throughout the process including with a view to assessing the budgetary impact of any decisions of the co-legislators and prevent further carve-outs from the U4Health programme.

In the event of new evidence or changes to this approach introduced by the co-legislators during the negotiations, the Committee on Budgets stands ready to assess the potential budgetary consequences.

Yours sincerely,

Johan Van Overtveldt

## ANNEX: ENTITIES OR PERSONS FROM WHOM THE RAPPORTEUR HAS RECEIVED INPUT

The rapporteur declares under his exclusive responsibility that he did not receive input from any entity or person to be mentioned in this Annex pursuant to Article 8 of Annex I to the Rules of Procedure.