

To Ms. Teresa Anjinho, the European Ombudsman

Brussels, September 18, 2025

Subject: Formal Complaint under Article 228 TFEU and Decision 94/262/ECSC, EC, Euratom – Failure by the European Commission and HaDEA to Ensure Legal Certainty, Transparency and Fairness in the 2025 EU4Health Operating Grant Procedure for FPA Holders

Dear Ms. Anjinho,

We, the undersigned civil society organisations holding Framework Partnership Agreements (FPAs) under the EU4Health Programme 2025–2026, together with a broad coalition of other health and patient-advocacy CSOs gathered around the EU4Health Civil Society Alliance, underscore the indispensable role that health NGOs play in safeguarding public health across Europe, and hereby submit this formal complaint concerning the unexplained suspension and administrative silence surrounding the call for the 2025 operating grants. Acting collectively on behalf of European Health NGOs, we represent thousands of professionals and networks across Europe dedicated to disease prevention, health equity, health management, mental health, preparedness and digital health - priorities enshrined in the EU4Health Programme.

I. NATURE AND CONTEXT OF THE COMPLAINT

1. Signature of FPAs; no call issued.

Despite the formal signature of valid FPAs in October 2024, no call for proposals was issued for 2025 operating grants; no legal decision or calendar had been communicated; FPA holders had remain uninformed months into the financial year, contrary to established practice.

2. Informal “guidance” and subsequent amendments.

On 24 April 2025, HaDEA notified FPA holders of new Commission “guidance” on EU reputational risk (Ref. Ares(2025)3314742). Subsequently, FPA holders were required to work with the HaDEA secretariat to significantly adjust their original workplan to comply with the new instruction, thereby raising expectations that the

Framework Agreements would be honoured. The guidance was delivered in an informal letter lacking the formal notification and reasoning required under Article 296 TFEU.

3. Late publication of the Work Programme without operating grants.

On 23 July 2025, European Commission published the EU4Health Work Programme for 2025, seven months into the calendar year, with no provision for and no budgetary allocation for operating grants.

4. Systemic opacity and marginalisation of civil society.

This unprecedented procedure - mirroring concerns raised by ClientEarth et al. in April 2025 regarding the sidelining of civil society - reveals a systemic pattern of opacity in Commission decision-making and consultation processes.

II. LEGAL BASIS

We invoke the following binding provisions and general principles of EU law:

- **Charter of Fundamental Rights (CFR), Art. 41** - Right to good administration (duty to be heard; to receive reasoned decisions; to have affairs handled within a reasonable time).
- **TFEU, Art. 15(1)** - Duty of EU institutions to act as openly as possible and ensure participatory democracy.
- **TFEU, Art. 296** - Duty to provide reasoned decisions for all acts.
- **Regulation (EU) 2018/1046 (Financial Regulation):**
 - Art. 195(4) - Operating grants must be signed within four months of the beneficiary's financial year start (i.e. by 30 April 2025 for calendar-year organisations).
 - Art. 188(2) & 195(1)(e) - Calls for proposals may only be waived in duly justified exceptional cases; direct awards to FPA holders require clear legal basis.
- **General principles:** Legal certainty; legitimate expectations (Mehibas Dordtselaan, Omnis, Vlachos); prohibition of unjust enrichment (Vlachos); good faith and contractual fairness (Technische Universität München); effective judicial protection (CFR, Art. 47; Del Plato and Others).

III. ALLEGED VIOLATIONS

1. **Breach of Art. 195(4) Financial Regulation**

No procedure has enabled FPA holders to submit grant applications and conclude grant agreements by the deadline of 30 April 2025.

2. **Failure to justify an exception under Art. 188(2)**

No “duly justified exceptional case” has been articulated to waive the 2025 call for proposals.

3. **Violation of the duty to give reasoned decisions (Art. 296 TFEU & CFR Art. 41)**

The 24 April 2025 HaDEA letter lacks the formal reasoning required for administrative acts, depriving stakeholders of grounds for legal challenge.

4. **Breach of transparency (Art. 15 TFEU)**

The Commission has provided no official calendar, rationale or public information - contrary to the EU’s obligation to conduct work “as openly as possible.”

5. **Violation of legitimate expectations**

FPA holders reasonably relied on the Commission’s consistent practice of annual operating grant calls; the abrupt deviation - without explanation - undermines legitimate expectations recognized by the Court of Justice.

6. **Unjust enrichment**

Civil society continues to deliver EU4Health objectives gratis, while the Commission enjoys outreach and visibility, fulfilling all elements of unjust enrichment under Vlachos.

7. **Breach of good faith and fair contractual balance**

The asymmetrical FPA model obliges civil society to deliver; the Commission’s silence and procedural withholding constitute arbitrary administrative conduct.

IV. REQUESTS FOR RELIEF

We respectfully ask your office to:

1. **Open an inquiry** into the Commission’s and HaDEA’s failure to launch the 2025 operating-grant call at the close of the FPA-amendment process, and into the absence of any formal decision or timetable thereafter.

2. **Request from the Commission and HaDEA**, and publish publicly by 30 September 2025, a reasoned decision addressing:
 - **Why** no operating-grant call was issued following the July amendment closure.
 - **Whether and on what legal basis** (e.g. direct award under Art. 195(1)(e)) FPA holders will nonetheless receive funding.
 - **How** the informal 24 April “guidance” (Ares(2025)3314742) fits within the Financial Regulation and FPA framework, and why it was not issued with the formal reasoning required by Art. 296 TFEU.
3. **Recommend remedial steps**, to be implemented no later than 31 October 2025, that ensure:
 - Immediate publication of the operating-grant call or, if the Commission opts against one, a fully reasoned, legally grounded alternative funding decision.
 - A clear procedural calendar for any remaining 2025 disbursements, restoring FPA holders’ ability to plan and deliver on EU4Health objectives.
 - Strengthened safeguards in future EU4Health cycles to prevent administrative silence and to uphold transparency, participation, and good administration.

We remain available to provide any further documentation or clarifications and look forward to your assessment of this urgent matter.

Yours sincerely,

Dr Milka Sokolović

Director General of the European Public Health Alliance (EPHA)

Co-Coordinator of the EU4Health Civil Society Alliance

On behalf of 25 co-signatory organisations:

- AIDS Action Europe
- Association of Schools of Public Health in the European Region (ASPHER)
- Association of European Cancer Leagues (ECL)

- Childhood Cancer International – Europe
- Correlation – European Harm Reduction Network (C-EHRN)
- Digestive Cancers Europe – DiCE
- European AIDS Treatment Group (EATG)
- European Alcohol Policy Alliance (Eurocare)
- European Association for Palliative Care
- European Health Management Association (EHMA)
- European Heart Network (EHN)
- European Liver Patients’ Association (ELPA)
- European Network for Smoking and Tobacco Prevention (ENSP)
- European Patients’ Forum (EPF)
- European Public Health Association (EUPHA)
- European Public Health Alliance (EPHA)
- EURORDIS – Rare Diseases Europe
- Fertility Europe
- Health Action International
- Infectious Disease Alliance
- International Sport and Culture Association (ISCA)
- Lungs Europe
- Psychedelic Access and Research European Alliance (PAREA)
- TB Europe Coalition
- Smoke Free Partnership (SFP)