To: Commissioner for Innovation, Research, Culture, Education and Youth and Commissioner for Health and Food Safety

CC: Directors General for DG RTD and DG SANTE, chairs and co-chairs of ITRE, ENVI, IMCO, permanent representations

13 December 2019

Dear Commissioner Gabriel,

Dear Commissioner Kyriakides,

As representatives of 43 organisations including patients, consumers, doctors, payers, HTAs and public interest organisations, we want to express our views on the European Partnership on Innovative Health.

Under the future Partnership between the European Commission and the healthcare sector industries, a considerable amount of public funds will be allocated to health research and innovation projects. Strong stewardship by the Commission, from inception to implementation, is crucial to ensure that this large investment serves the public interest.

However, the need for strong leadership from the public sector is undermined by the fact that there is already a Partnership Draft Strategic Research Agenda proposed by the five largest European health industry associations. Furthermore, the launch by EFPIA and other industry partners of a “public consultation” on this draft agenda sends the signal that the private sector is taking the reins on the priority setting of the Public-Private Partnership. Such an approach risks giving priority to commercial strategies, entrenching conflicts of interest and seeing vast amounts of taxpayers’ money diverted to industry’s priorities rather than public health needs, without ensuring sufficient public return on public investment.

Numerous evaluations of the previous health partnership, the Innovative Medicines Initiative (IMI) have criticised the lack of inclusivity in the choice of research priorities, the governance structures and the dominance of large industry players, and have warned that scientific advisory groups have “no significant influence” on shaping the agenda. The European Commission should be seeking to reform the next partnership to ensure health authorities, academics, public health professionals and civil society organisations are robustly engaged in agenda setting, rather than taking a step backwards and entrenching the dominance of commercial interests.

A lack of transparency around funding, beneficiaries, governance, data and results, as well as a lack of alignment between industry’s research priorities and the public interest, has resulted in questionable output for public healthcare systems and the use of public money.

We urge the European Commission to safeguard that the public interest is at the core of the future European Partnership on Innovative Health by ensuring:

1. **Priority Setting driven by public health needs**
2. **Transparent, balanced and inclusive governance structures**
3. **Public return on public investment and ensuring equitable access to publicly funded R&I**
4. **Full transparency on R&I investments**
5. **Open science**
6. **Sensitive health policy issues to be discussed in inclusive multi-stakeholder platforms with strong stewardship from public authorities**

We welcome the possibility of a meeting to further discuss our proposals, which are detailed on the following page.

Supporting organisations

1. AAJM - Asociación por un Acceso Justo al Medicamento (Spain)
2. Access to Medicines Ireland (Ireland)
3. AIDES (France)
4. AIDS Action Europe
5. AOK Bundesverband (Germany)
6. ARAS - Romanian Association Against AIDS (Romania)
7. BEUC - The European Consumer Organisation
8. Bulgarian Association for Patients' Defense (Bulgaria)
9. Commons Network
10. EKPIZO (Greece)
11. European Academy of Paediatrics
12. European AIDS Treatment Group
13. European Alliance for Responsible R&D and Affordable Medicines
14. European Association of Hospital Pharmacists - EAHP
15. European Institute of Women's Health
16. European Public Health Alliance – EPHA
17. European Social Insurance Platform - ESIP
18. Global Health Advocates
19. Grupo de Ativistas em Tratamentos (Portugal)
20. Health Action International - HAI
21. HOPE - European Hospital and Healthcare Federation
22. International Association of Mutual Benefit Societies - AIM
23. Just Treatment
24. Ludwig Boltzmann Institute for HTA - LBI-HTA (Autria)
25. Main Association of Austrian Social Security Institutions – SV (Austria)
26. Mario Negri Institute for Pharmacological Research (Italy)
27. Medecins du Monde (Greece)
28. Mental Health Europe
29. MSF Access Campaign
30. National Health Care Institute - ZIN (The Netherlands)
31. Prescrire
32. ReAct Europe
33. Romanian Health Observatory (Romania)
34. Salud por Derecho (Spain)
35. Social Security Institution of Finland (Finland)
36. SOMO
37. Standing Committee of European Doctors - CPME
38. STOPAIDS (UK)
39. T1International
40. Test Aankoop/Test Achats (Belgium)
41. Transparency International Health Initiative
42. Universities Allied for Essential Medicines (UAEM) Europe
43. Wemos (The Netherlands)

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We urge the European Commission to guarantee that the public interest is in the driving seat of the future European Partnership on Innovative Health.

More specifically, we call upon the Commission to ensure the following:

1. **Priority setting driven by public health needs**

The future health partnership should fund R&I initiatives that focus on unmet public health needs, lead to products and services with added therapeutic value and contribute to the sustainability of our healthcare systems.

The EU should adopt priority setting procedures that ensure balanced stakeholder involvement, including independent civil society organisations, patients, consumers and payers.

2. **Transparent, balanced and inclusive governance structures**

The governance structures of the future innovative health partnership should ensure a balanced representation of relevant stakeholders including public health civil society organisations, patients, consumers and payers. Merely opening up the governance to more industry groups will not address the fundamental governance issues. In order to increase public accountability, greater transparency is needed in the decision-making processes including publication of full minutes of meetings.

3. **Public return on public investment and ensuring equitable access to publicly funded R&I**

The EU should attach provisions to public funding to tackle affordability, accessibility, availability and efficiency along all the R&I stages and explore various forms of IP management and licensing, including equitable licensing.

Moreover, the health partnership should include indicators for measuring the societal impact of EU investment, clearly defined in a transparent multi-stakeholder process, be linked to SDGs and have robust monitoring via targeted indicators.

4. **Full transparency on R&I investments**

The EU should ensure that public investment within the health partnership is met with complete transparency regarding the costs of research, development and production.

The EU should make research consortium agreements under its partnerships available through publication. This should include the public (EU and ideally national public support) and private shares (in-cash and in-kind) of the contribution to the research consortium.

5. **Open science**

The health partnership should mandate open access and open data requirements to ensure that knowledge gained with the support of public funding is accessible and reusable. Compliance with EU data protection rules must be ensured, and strong data security mechanisms must be put in place. Depending on the types of research data (personal/non-personal) different modalities of data sharing should be considered.

To prevent abuses, when implementing the Regulation on Horizon Europe the EU should further specify the grounds for derogations of open data requirements. Public interest considerations must prevail.

6. **Sensitive health policy issues to be discussed in inclusive multi-stakeholder platforms and with strong stewardship from public authorities**

Partnerships with the industry in a crucial leadership role are not the appropriate fora for developing policy on sensitive issues where there is a high risk of conflict of interest from commercial partners. For example, topics such as the regulatory approval of new health innovations, the ways we pay for innovation and the use of citizens' health data. While uses of big biomedical data can lead to new scientific discoveries, it must be ensured that personal data is duly protected. Such issues are matters of public interest and should only be discussed in multi-stakeholder platforms with equal involvement of civil society and with strong stewardship from public authorities. Unless the governance and accountability mechanisms of the future Innovative Health partnership are revised, it cannot be considered an appropriate platform to address such sensitive topics.