To: Permanent Representations (health attachés)

09 September 2021

Subject: Joint call for enhanced clinical trial transparency and good governance in the European Medicines Agency extended mandate

Dear Health attaché,

We, the undersigned 28 organisations, urge the Council to ensure that the Regulation for a reinforced EMA role leads to enhanced clinical trial transparency and upholds good governance. As members of the European Alliance for Responsible R&D and Affordable Medicines representing patients, consumers, health professionals, and civil society, we consider essential that these elements are reflected in the final text agreed at trilogues.

To avoid unnecessary duplications and to accelerate the development of new therapies and vaccines during a public health emergency, it is crucial that information on clinical trials is made available in a timely, user-friendly, and complete manner as proposed by the European Parliament (amendment 107 of the EP text).

The proposed amendment ensures that study protocols, summary results, clinical data submitted in support of a marketing application, and the eventual approval decision, are published in a timely manner and with more details than during normal times. We support this call and believe this should also be part of a wider effort outside of public health emergencies.

If the EU wishes to be better prepared and to have a more effective response to future health crises, it will need to ensure the availability and accessibility of medicines across Member States. Reinforcing the EMA's role would be a critically needed step towards better preparedness and response to public health emergencies. In doing so, the EU should not miss the opportunity of ensuring transparency in clinical trials and reaffirming its role as a global leader in this area.

The Council should also support the EP proposed amendments regarding the adoption of an inclusive definition of shortages of medicines comprising shortages caused by the withdrawal of products from the market for commercial reasons; the participation of patients and consumers in related governance and activities of the involved Steering Groups; and the inclusion of requirements for transparency and to prevent conflicts of interest.

We would like to take the opportunity to refer to the Clinical Trial Regulation and highlight the need to ensure that the monitoring dashboard of the new Clinical Trials Information System (CTIS) is made publicly accessible in full.

We look forward to further exchanges to address the transparency of clinical trials as well as shortages of medicines (within and outside public health emergency times). It is imperative that the voice of patients, consumers, professionals, and civil society

organisations are heard in further discussions and initiatives to address these and other issues affecting access to affordable medicines.

Please find enclosed an Annex where we develop our position further. For your information, this letter will be shared with the European Commission, European Parliament and the EMA.

The undersigned organisations would welcome the opportunity to meet with you to discuss our demands.

1. Access to Medicines Ireland
2. AIDES
3. Asociación por un Acceso Justo al Medicamento (AAJM)
4. The European Consumer Organisation (BEUC)
5. BUKO Pharma-Kampagne
6. Centre for Research on Multinational Corporations-SOMO
7. Consilium Scientific
8. Corporate Europe Observatory (CEO)
9. CurbingCorruption
10. Drugs for Neglected Diseases initiative (DNDi)
11. EPHA
12. EXPIZO
13. France Assos Santé
14. Global Health Advocates (GHA)
15. Health Action International
16. International Society of Drug Bulletins (ISDB)
17. Médecins du Monde
18. Médecins Sans Frontières (MSF) Access Campaign
19. NoGracias
20. Prescrire
21. Public Eye
22. Salud por Derecho
23. Test Aankoop/Test Achat
24. The Pharmaceutical Accountability Foundation+
25. Transparency International Global Health
26. TranspariMED
27. Universities Allied for Essential Medicines – UAEM
28. Wemos

This letter is supported by 28 organisations and it was coordinated by the European Alliance for Responsible R&D and Affordable Medicines

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Annex- Recommendations for enhanced clinical trial transparency and good governance in the EMA extended mandate

1. Enhancing clinical trial data transparency during public health emergencies and beyond

The COVID-19 pandemic has highlighted the importance of addressing shortages of critical medicines and coordinating clinical trials for the development of new medicines. It has also shown how lack of transparency on clinical trials threatens to delay the development of critically needed therapies and vaccines[1]Additionally, billions of public funds have been spent on COVID-19 R&D and clinical trials[2] as well as on expensive COVID-19 treatments[3]. Transparency of clinical trial data prevents duplication and allows for crucial insights into treatment effectiveness, and therefore enables more efficient expenditure of such funds. Transparency is not only urgent in a public health emergency context; it is also a crucial responsibility towards society.

On the contrary, lack of transparency in clinical trials undermines their usefulness for research and may lead to duplicative efforts and delays in the development of new therapies and vaccines, ultimately affecting patients and health systems. Such delays and duplications are particularly detrimental during public health crises[4].

In addition, past experience shows that public visibility of the trial reporting and data management performance of the various stakeholders involved in uploading and managing European clinical trial registry data, including the performance of trial sponsors and National Competent Authorities, can significantly and at zero cost increase the quality and quantity of trial data available to patients, medical professionals and public health agencies, both during public health emergencies and beyond.

Looking ahead, we call on Member States and the EMA to make the most of the Clinical Trial Regulation and ensure that any Clinical Trials Information System (CTIS) monitoring data capturing stakeholders' performance is made publicly available in full and on an ongoing basis through the public CTIS interface. This will facilitate public accountability and translate into greater compliance.

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[1] See, among others, Transparency International Global Health, For Whose Benefit? Transparency in the development and procurement of COVID-19 vaccines, http://ti-health.org/wp-content/uploads/2021/05/For-Whose-Benefit-Transparency-International.pdf, highlighting that a high proportion of Covid vaccine trials have been announced through the media without the publication of results and real data analysis; Irene Romero Bhathal UAEM, COVID Clinical Trials in Spain Fragmentation, Duplication and Transparency Spain, 26 November 2020, https://www.transparimed.org/single-post/covid-clinical-trials-research-waste-spain; Till Bruckner (TranspariMED), Risk of research waste in COVID-19 drug trials conducted in Europe, 18 June 2020, https://docs.wixstatic.com/ugd/01f35d_a44c29998c814119bb8dd6bd24703122.pdf; and See the Joint Statement on transparency and data integrity - International Coalition of Medicines Regulatory Authorities (ICMRA) and the World Health Organization (WHO) at Joint Statement on transparency and data integrity - International Coalition of Medicines Regulatory Authorities (ICMRA) and the World Health Organization (WHO)

[2] €93 Billion Spent By Public Sector On COVID Vaccines And Therapeutics In 11 Months, Finds New Research

[3] EU makes 1 billion-euro bet on Gilead's COVID drug before trial results

[4] Tanveer, S., Rowhani-Farid, A., Hong, K., Jefferson, T. and Doshi, P., 2021. Transparency of COVID-19 vaccine trials: decisions without data. BMJ Evidence-Based Medicine.

In addition, we call on the EU institutions to ensure that information on clinical trials is communicated in a timely, user-friendly and comprehensive manner during public health crises. This must be addressed in the proposed Regulation for a reinforced EMA role.

2. Good governance in the new EMA structures

In addition, the Regulation for a reinforced EMA role must ensure meaningful engagement of patients, consumers and healthcare professionals in discussions on shortage prevention and management, as well as strong transparency and conflicts of interest requirements in the new structure that will be established under the EMA. This is key to ensure that decisions on medicine shortages are aligned with the interests of those that suffer more from its consequences, as well as the independence and impartiality of processes to foster public trust.