

Professor Giulio Rasi  
Executive Director  
European Medicines Agency  
Domenico Scarlattilaan 6  
1083 HS Amsterdam  
The Netherlands



Madrid, 31 August 2020

Dear Mr Rasi,

With this letter, Access Info Europe, TranspariMED, and 26 other health organisations, transparency associations, and academics would like to express their concern that you are not accepting access to documents requests via email, either in general or via request platforms such as AsktheEU.org.

Access Info Europe contacted you on 5 August 2019 asking that EMA provides both Access Info Europe and the European public with an email address to which access to documents applications can be sent. To this date, no email address has been provided by EMA. We urge you to reply to our request, and provide an email address that can be used by European Union citizens to request documents held by EMA.

Requesting documents via email is consistent with the European Medicines Agency's policy on access to documents (Policy/0043 of 4 October 2018) and its Annex on implementing Regulation (EC) No 1049/2001, which, at Paragraph 2.1 on Requests for Access, establishes that: *"Applications for access to EMA documents, which are not publicly available, shall be made in writing including electronic form, and in a sufficiently precise manner to enable EMA to identify the document(s)."*

This provision is also in line with Article 6.1 of EU Regulation 1049/2001, which permits requests by email in one of the languages of the European Union. Regulation 1049/2001, which implements Article 15 of the TFEU, does not permit EU institutions, bodies, and agencies to require that requests be submitted via the institution's portal or official website.

At the moment, EMA only allows EU citizens and residents to make a formal request for access to EMA documents that are not already published on EMA's official website (<https://www.ema.europa.eu/en/about-us/contact/send-question-european-medicines-agency>). A further problem with this online form is that it makes it obligatory to provide the name of your

The European Medicines Agency plays an essential role in "fostering scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the European Union". In these unique times, it is particularly important that the work of the Agency, as well as of other health-related institutions, be as transparent as possible. Such transparency contributes to knowledge-sharing, to combatting fraud and corruption in the health sector, and thus helps to save lives. Transparency is also a tool in combating the virus and improving the European health policy.

AsktheEU.org takes forward this goal by allowing European Union citizens and residents to exercise their right of access to documents. It is an online platform run by Access Info Europe – one of the leading organisations working on government transparency in Europe – through which civil society, journalists, researchers, and members of the public can request EU documents and monitor these

requests on the portal. The responses are public, so that other citizens can benefit from them, thereby increasing the transparency and accountability of EU institutions.

Every time a request is sent via AsktheEU.org, the system generates a unique email address, which allows all communication around a particular request to appear on the same page of the platform. The EU institution will receive it as it would a normal email. Please note that your email address will never be made public or shared with the AsktheEU.org users. Simply, it will be used by the AsktheEU.org Team to set up the system and make sure that all requests addressed to EMA will be sent to that email address.

We also note that the European Ombudsman recently recommended to Frontex to “respond to requests for public access to documents via online portals where this is the express wish of the applicant or [in] the means by which the request has been received” (Decision in case 104/2020/EWM).

We therefore ask you to reconsider providing us with an email that can be used on AsktheEU.org, so that scientists, doctors, and the European civil society become aware of the work you do, and get access to EMA official documents. We also urge you to make this email address available on your website, so that this means of communication can be used by all those other citizens who do not request information via AsktheEU.org.

Your sincerely,

1. Access Info Europe
2. Access to Medicines Ireland
3. ALTER-EU
4. BUKO Pharma-Kampagne
5. Campaign for Freedom of Information Scotland
6. Clean Air Action Group
7. Consumer Association the Quality of Life EKPIZO
8. Corporate Europe Observatory
9. Curbing Corruption
10. Föreningen för Digitala Fri- och Rättigheter DFRI
11. Global Health Advocates
12. Healthwatch
13. Homo Digitalis
14. LobbyControl
15. Öffentlichkeitsgesetz.ch
16. Open Knowledge Foundation Germany
17. Right To Know CLG
18. Salud por Derecho
19. Transparency International EU
20. Transparency International Health Initiative
21. TranspariMED
22. Wemos
23. Wissenschaftsladen Wien

24. John R. Campbell, Editor-in Chief of Open Anthropological Research and Emeritus Reader in the Anthropology of Africa and Law, School of Oriental & African Studies
25. Julia Keseru, Executive Director, Engine Room
26. Ludovica Jona, Freelance Journalist
27. Samuel Stolton, Digital Editor, Euractiv
28. Siem Eikelenboom, Investigative Reporter, Follow the Money