European Commission: taken to task by the Ombudsman for lack of transparency

● Following complaints on excessive response times, the European Ombudsman has reminded the European Commission that EU citizens have the right to access to administrative documents and that access delayed is access denied.

The transparency of European institutions and agencies is one of the fundamental principles of the European Union (EU), and the obligations of these institutions and agencies upon receiving a request for access to a document they hold are defined in an EU regulation (1). If the request is refused, the applicant may send a "confirmatory application", which must be dealt with within 30 working days. If the request is refused a second time, the applicant may then submit a complaint to the European Ombudsman. In 2022, following a series of complaints, the European Ombudsman opened an inquiry into the handling of these requests by the European Commission (2).

The Ombudsman found that 85% of the 355 confirmatory applications received in 2021 were not dealt with within the maximum legal time limit of 30 working days. In some cases, the Commission took several months to respond, and it took 2 years to send a journalist documents requested about the purchase of 1.5 million non-compliant medical masks at the outset of the covid-19 pandemic (2).

In its defence, the Commission pointed to the time it needed to obtain any clarifications regarding a request, identify the right documents, redact certain passages, and consult any third parties that might object to disclosure (such as a pharmaceutical company) (2). The Ombudsman's inquiry also reveals that the confirmatory applications often pertained to issues of great public importance, and that the consultation of the third parties concerned by document disclosure was often launched after the time limit had already expired. The Commission consults such parties in order to reduce the risk of legal action, but typically accepts their position. The Ombudsman argues that not all cases require such a cautious approach (2).

The findings of this inquiry reflect our own experience, over the past two decades, of the handling of document requests sent by Prescrire to the European Medicines Agency (EMA). This has included excessive delays in response times, procedures that prevent applicants from submitting complaints, and a strategy of avoiding legal action by the pharmaceutical companies concerned by the disclosure (1).

In her recommendations to the Commission, the Ombudsman draws attention to the obligations that apply to institutions such as the EMA, and the fact that access to administrative documents is a right that enables citizens to participate in EU decision-making. Access delayed is access denied, and prevents citizens from being able to act in a timely manner (2).

The EMA admits that compliance with the response times mandated in the EU is not one of its key priorities (3). Transparency about evaluation data is, however, essential for patients and healthcare professionals. It would be useful if the Ombudsman launched an in-depth inquiry into the EMA's lack of transparency, and reported on the matter to the European Parliament, as she did in September 2023 in relation to the Commission (2).

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References **1-** Prescrire Editorial Staff "European Medicines Agency: transparency policy marred by too many failings" *Prescrire Int* 2022; **31** (237): 130-139. **2-** European Ombudsman "Recommendation on the time the European Commission takes to deal with requests for public access to documents (...)" 24 March 2023 + 21 September 2023. **3-** EMA "European Medicines Agency Final programming document 2023-2025" 2023: 178 pages.

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