

Prescrire's response to the Public consultation on the European Ombudsman's Strategy Towards 2019 (deadline 28 July 2017)

1. How successful have we been in implementing and achieving the objectives and the priorities of the strategy?

Prescrire applauds the European Ombudsman's work over the past several years, most particularly in the areas of transparency and access to documents, prevention of conflicts of interest, and public participation in the European Union decision-making process (transparency of "Trilogues")

The European Ombudsman has played a fundamental role in improving access to documents held by the European Medicines Agency (EMA).

Thanks to the European Ombudsman's interventions, the EMA has been encouraged to become more transparent. Whether it be via investigations launched on their own initiative or as a result of complaints they have received (including from ourselves), interventions by the Ombudsman have greatly contributed to improving existing public policies and practices, most particularly as regards access to documents pertaining to the marketing authorisation of medicines. We strongly urge the Ombudsman to carry on with this work, in keeping with the objectives and priorities outlined in their 2019 strategy, which we find to be satisfactory and relevant.

7. Are there any new specific topics or systemic issues to which the Ombudsman should dedicate increased resources?

We at Prescrire take pride in the Ombudsman's recent initiative to open an inquiry into the dealings between the European Medicines Agency and pharmaceutical companies during the phase leading up to applications for marketing authorisation. For many months now, Prescrire has been expressing concern as to the lack of transparency in the dealings between drugs manufacturers and the EMA, particularly scientific advice given in the phase leading up to an application for marketing authorisation (and most notably in the context of plans such as "Adaptive Pathways" or "PRIME") and the risk of institutional capture which could result from this.

We fervently hope that the European Ombudsman will continue to see to it that the EMA strictly applies the Regulation on Clinical Trials by granting access to Clinical Study Reports (CSR), in keeping with the legislative intent expressed.

8. Is there anything else you would like to share with us in terms of general feedback, ideas or suggestions?

For Prescrire, the European Ombudsman has played a crucial role in improving transparency and access to documents held by the EMA. On numerous occasions, the Ombudsman has seen to it that the EMA correctly applies EC Regulation n° 1049/2001 outlining the rules for public access to the documents of European institutions.

Here are some important matters which have been taken on by the European Ombudsman, in the interest of streamlining the functioning of the European Union, including the EMA, and encouraging greater transparency for the benefit of European citizens:

- Transparency of Trilogues
- Management of conflicts of interest
- The European Medicines Agency's new transparency policy, including access to the results of clinical trials
- Investigation of complaints regarding access to documents and to information held by the EMA pertaining to clinical drugs trials, including Prescrire's complaints over repeated and unjustified refusals to provide documents and unacceptably long delays in responding.