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European Medicines Agency still lags in providing key documents

In August 2010 Prescrire filed 5 complaints with the EU Ombudsman, citing repeated refusals by the European Medicines Agency (EMA) to provide documents and information, in particular concerning drugs with a negative harm-benefit balance. After EMA's refusal in January 2011 to deliver most of these documents, Prescrire decided in March 2011 to maintain all 5 of its complaints.

The points contained in Prescrire's complaints reflect maladministration by the EMA, including:
– unacceptably long delays before disclosing information, particularly about adverse effects;
– blatant refusals to provide documentation.

Overall, EMA's responses are insufficiently explicit and rarely allow requests to be fine-tuned.

Despite repeated urgings to the contrary, EMA still interprets EC Regulation No 1049/2001 concerning public access to administrative documents in a very restrictive manner. On the other hand its interpretation of "confidential document" is boundless.

Information about the adverse effects of drugs is scientific data and EMA has no right to refuse access to documents containing such information, on the pretext of their commercially sensitive nature or the fact that an administrative procedure is still underway.

EMA must provide timely access to a comprehensive register of all the documents it produces, and all those it receives.

Prescrire calls upon EMA to:
– provide public access to the raw data held in its databases, especially the EudraVigilance database;
– provide timely public access to the minutes and scientific opinions of all of its committees, working parties and other groups;
– provide timely public access to conflict of interest statements for all of its experts and participants of committees, working parties and other groups;
– provide more constructive responses to concerned parties, and to help them determine how best to formulate their requests where appropriate.

Advocacy groups Health Action International (HAI) Europe and the Medicines in Europe Forum have also spoken out in favour of greater transparency, in their joint response to the HMA/EMA guidance document on the identification of commercially confidential information and protection of personal data within the structure of the marketing authorisation application, dated 31 August 2011.

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