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Prescrire files a complaint against the European Medicines Agency (EMA)

Prescrire filed a complaint on 30 August 2010 with the EU Ombudsman, P. Nikiforos Diamandouros, citing EMA's repeated refusals to supply documents and information, in particular on drugs with an unfavourable risk-benefit balance. Or because the documents provided were largely censored, and therefore unusable. The reason given by EMA for these refusals was often the protection of trade secrets.

The data analysed in *Prescrire* and *Prescrire International* come mainly from clinical trials. The results of some of these trials are published in international journals. Others are not published, but are none the less supplied to the agencies in charge of granting marketing authorisations and used in the drug's evaluation, in other words to assess its risk-benefit balance for the patients for whom it is prescribed.

Other documents, established after drugs are on the market, also contain essential information concerning the risks once the drugs have been used by a large number of patients. These "PSURs" (Periodic Safety Updated Reports) reflect the adverse effects reported to the regulatory bodies in charge of collecting pharmacovigilance reports.

Several widely prescribed drugs have been withdrawn from the market recently due to the serious, and sometimes fatal, adverse effects to which patients have been subjected, for example: the anti-inflammatory *rofecoxib* (ex-Vioxx°); weight-loss drugs *rimonabant* (ex-Acomplia°) and *benfluorex* (ex-Mediator°); cholesterol-lowering drug *cerivastatin* (ex-Staltor°); etc. Yet the existence of these risks could have been found in the results of the clinical trials, or in the PSURs.

Prescrire's complaint concerns 5 particularly unacceptable refusals:

- refusal to send a Reference Member State assessment report on *rimonabant*, a dangerous anti-obesity drug that was withdrawn for safety issues from the European market some months after Prescrire's request;
- refusal to provide Prescrire with any Periodic Safety Updated Reports (PSURs);
- EMA's refusal to provide Prescrire with mock-up packaging;
- refusal to give access to clinical data on the *dextropropoxyphene + paracetamol* combination;
- EMA's refusal to provide Prescrire with the assessment report established by the member state medicines agency designated by the European authorities to determine the safety of topical *ketoprofen*.

For more information, and for the full text of the complaint, see the "Spotlight" section online at www.english.prescrire.org