European Ombudsman

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Ombudsman welcomes release of adverse reaction reports by European Medicines Agency

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The European Ombudsman investigates complaints about maladministration in the EU institutions and bodies. Any EU citizen, resident, or an enterprise or association in a Member State, can lodge a complaint with the Ombudsman. The Ombudsman offers a fast, flexible and free means of solving problems with the EU administration.

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The European Ombudsman, P. Nikiforos Diamandouros, has welcomed the European Medicines Agency's (EMA) release of adverse reaction reports related to *Septrin*, a medicine for the treatment of bacterial infections. This follows a complaint from a law firm, whose request for access to these reports had been refused. EMA eventually followed the Ombudsman's recommendation to release the adverse reaction reports.

The Ombudsman stated: "I commend the important progress that EMA has recently made in improving the transparency of its work. Such improvements ensure that citizens will have greater trust in EMA, thus increasing both its legitimacy and its effectiveness in carrying out its important work in the field of public health."

Access to adverse reaction reports on anti-bacterial medicine

The London-based European Medicines Agency approves and monitors medicines placed on the EU market, with a view to protecting public health. It receives information concerning suspected adverse reactions to drugs from the competent authorities in the Member States and from pharmaceutical companies.

A Greek law firm asked EMA for public access to a range of documents, including adverse reaction reports related to *Septrin*, a medicine for the treatment of bacterial infections. EMA refused, arguing that it needed to protect commercial interests. The Ombudsman's investigation led him to conclude that the documents in question did not contain commercially confidential information, but that personal data contained in the reports needed to be removed before disclosure. EMA eventually followed the Ombudsman's recommendation to disclose the documents, after removing personal data.

The full decision is available at:
http://www.ombudsman.europa.eu/cases/decision.faces/en/11119/html.bookmark