European Ombudsman

Ombudsman welcomes release of adverse reaction reports by the European Medicines Agency

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The European Ombudsman, **P. Nikiforos Diamandouros** , has welcomed the announcement of the European Medicines Agency (EMA) that it will release documents related to a drug used to treat severe forms of acne. The complainant, an Irish citizen, had asked for the release of reports concerning suspected adverse reactions to the drug. EMA initially refused access, arguing that EU transparency rules do not apply to adverse reaction reports. The Ombudsman did not agree. He called on EMA to reconsider its refusal to give access to the documents. EMA accepted the Ombudsman's recommendation and announced the release of the reports.

Mr Diamandouros said: "I commend EMA's constructive approach in this important case. EMA's work has a direct impact on the health of European citizens. It is, therefore, crucial to give the widest possible access to documents and to pursue a pro-active information policy for the benefit of citizens."

Adverse reaction reports related to anti-acne medication

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

In April 2008, an Irish citizen asked EMA for access to documents containing details of all suspected serious adverse reactions relating to an anti-acne drug. His son had committed suicide after taking the drug.

EMA refused his request, arguing that the EU rules on access to documents did not apply to reports concerning suspected serious adverse reactions to drugs.

Following his investigation into the Irish citizen's complaint, the Ombudsman concluded that the EU rules on access to documents apply to all documents held by EMA. He, therefore, recommended that EMA review its refusal to grant access to the adverse reaction reports. The Ombudsman also suggested that, as part of a proactive information policy, EMA could provide additional clarifications to make it easier for the public to understand such data and their significance.

EMA accepted the Ombudsman's recommendation to give access to the documents by announcing the release of the adverse reaction reports. The Ombudsman will take account of EMA's announcement when drafting the decision closing his investigation.

The Ombudsman's full recommendation is available at:

http://www.ombudsman.europa.eu/cases/draftrecommendation.faces/en/4810/html.bookmark [Link]