Ombudsman: European Medicines Agency should disclose clinical reports on anti-obesity drugs

Press release no. 13/2010 - 07/06/2010

The European Ombudsman, **P. Nikiforos Diamandouros** , has called on the European Medicines Agency (EMA) in London to grant access to clinical study reports and trial protocols for two anti-obesity drugs. This follows a complaint from Danish researchers in the field of healthcare who wanted to conduct an independent analysis. EMA refused their request for public access to these documents on the grounds that disclosure would undermine the drug producers' commercial interests.

During his investigation, the Ombudsman inspected the relevant reports and protocols. He concluded that their disclosure would not undermine commercial interests. The Ombudsman recommended that EMA should disclose the documents or else give convincing arguments as to why access cannot be given.

EMA invokes obligation to protect commercial interests

The European Medicines Agency evaluates and supervises medicinal products placed on the EU market, with a view to protecting public health. In this capacity, it receives clinical study reports and trial protocols from drug producers seeking to obtain marketing authorisation.

In 2007, researchers of a Danish research and information centre in the field of healthcare requested access to clinical study reports and corresponding trial protocols for two anti-obesity drugs. They explained that they wanted to conduct an independent analysis given that, in their view, biased reporting on drug trials was common. EMA refused disclosure on the grounds that it would undermine the drug producers' commercial interests.

In October 2007, the Danish researchers turned to the Ombudsman. They claimed access to the documents and defended their view that concerns for patients' welfare should be given priority over concerns for the commercial interests of the drug industry.

During his investigation, the Ombudsman inspected the relevant reports and protocols. He concluded that the documents did not contain information on the composition of the anti-obesity drugs, nor did they contain other commercially confidential information. In his view, their disclosure would consequently not undermine commercial interests. The Ombudsman, therefore, criticised EMA's refusal to grant access to the reports and protocols as an instance of maladministration. He called on EMA to disclose the documents or provide a convincing explanation as to why access cannot be given. EMA is invited to submit a

detailed opinion by 31 August 2010.

To read the Ombudsman's recommendation, please go to:

http://www.ombudsman.europa.eu/cases/draftrecommendation.faces/en/4883/html.bookmark