European Ombudsman

Press release No. 10/2012

Ombudsman calls for more transparency concerning medicines for children

4 June 2012

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 called on the European Medicines Agency (EMA) to increase the transparency of its procedures for ensuring that children can benefit from new medicines. This follows a complaint from two pharmaceutical companies which were required by EMA to test the suitability for children of their heart failure medicine. They alleged unfair treatment because other pharmaceutical companies had been exempted from the obligation to test similar products. The Ombudsman concluded that EMA did not properly disclose its assessments in these cases. He called on the Agency to make its procedures more transparent in the future.

Testing medicines to treat children suffering from heart failure

In order to protect better the health of children, the EU adopted a Paediatric Regulation in 2006. The Regulation includes an obligation requiring pharmaceutical companies to conduct tests to determine whether and how their medicines can be used to treat children. EMA, based in London, is responsible for ensuring that pharmaceutical companies comply with their obligations under the Paediatric Regulation.

In October 2009, two pharmaceutical companies lodged a complaint with the Ombudsman because EMA was obliging them to test how their heart failure medicine could be used to treat children. They alleged discrimination, since EMA had exempted two similar medicines from the requirement to be subjected to such tests.

EMA stated that the limited number of children suffering from heart failure meant that only one heart failure medicine could be tested effectively. According to EMA, the complainants' medicine was the most promising, and thus the most appropriate medicine to test.

The Ombudsman conducted an in-depth investigation into the assessment procedures for the different medicines. He came to the conclusion that EMA was indeed entitled to oblige the complainants to conduct the tests. However, he criticised EMA's failure to ensure adequate transparency in its decision-making process. He called on EMA to document fully and disclose its assessments in the future and also to introduce relevant guidelines in this respect. He asked EMA to reply to his recommendation by 30 September 2012.

The full recommendation is available at:
http://www.ombudsman.europa.eu/en/cases/draftrecommendation.faces/en/11553/html.bookmark