Ombudsman applauds European Medicines Agency's adoption of new transparency policy

The European Ombudsman, **P. Nikiforos Diamandouros** , welcomes the announcement by the European Medicines Agency (EMA) in London that it will comply with EU transparency rules. This follows EMA's decision to publish a new access to documents policy aimed at giving the public much broader access to documents in its possession.

Mr Diamandouros commented: "I am greatly encouraged and applaud EMA's constructive approach to improving its transparency policy. EMA's work has a direct impact on the health of European citizens. It is, therefore, crucial that EMA give the widest possible access to documents and pursue a pro-active information policy for the benefit of citizens. By taking this important policy step, EMA has given wider effect to recommendations I made to the Agency earlier this year in connection with two important cases concerning access to documents. I look forward to further good cooperation with EMA in the future."

EMA grants access to clinical study reports for anti-obesity drugs

In the most recent case, made public today, the Ombudsman welcomed EMA's announcement that it will grant access to clinical study reports and trial protocols for two anti-obesity drugs. This followed a complaint from Danish researchers working in the field of healthcare, who wanted to conduct an independent analysis of the relevant data. EMA had initially 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. In his view, these documents did not contain information on the composition of the anti-obesity drugs involved. Nor did they contain commercially confidential information. Accordingly, he concluded that their disclosure would not undermine commercial interests and called on EMA to disclose them. EMA accepted the recommendation and announced the release of the study reports and protocols. To read the Ombudsman's decision, please go to: http://www.ombudsman.europa.eu/cases/decision.faces/en/5459/html.bookmark

EMA discloses adverse reaction reports on anti-acne drug

In April 2010, the Ombudsman recommended that EMA disclose reports concerning suspected adverse reactions to a drug used to treat severe forms of acne. The complainant, an Irish citizen, had asked for the release of the reports. EMA initially refused access, arguing that EU transparency rules did not apply to the reports. The Ombudsman did not agree. In August 2010, EMA accepted the Ombudsman's recommendation to release the reports. To

read the Ombudsman's recommendation, please go to:
http://www.ombudsman.europa.eu/cases/draftrecommendation.faces/en/4810/html.bookmark