

EU Ombudsman: Transparency rules apply to all documents held by EMA

In 2008, an Irish citizen asked the European Medicines Agency for access to reports on suspected adverse reactions to a drug used to treat severe forms of acne. The EMA refused this request and the citizen turned to the EU Ombudsman, Mr. P. Nikiforos Diamandouros.

Diamandouros has concluded that:

“Since its work has a direct impact on the health of European citizens, its is of utmost importance for EMA to give the widest possible access to documents and also to pursue a pro-active information policy for the benefit of citizens.”

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What does this mean for public access to EMA documents? The Ombudsman cautions that adverse reaction reports won’t automatically be open book. But, exceptions to the rule need to be made.

It’s striking that information about medicines safety, particularly the data generated by citizens, is actually held out of their reach. The EU Ombudsman’s added support only strengthens our repeated requests for access to information that can affect our health.

See HAI, MiEF and ISDB joint response to September 2009 consultation “[EMEA transparency policy falls short](#)” (pdf)

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