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Media and Public Relations

Press release

Court of Justice upholds EMA's approach to transparency

EMA welcomes today's two appellate judgments by the Court of Justice[1] that confirmed, in clear and unambiguous terms, the right of citizens for access to clinical study and toxicology reports submitted to EMA for the purpose of the granting of a marketing authorisation for human and veterinary medicinal products.

"Transparency is an important feature of the Agency's operations. We welcome today's judgments and will continue to work to secure transparency on medicinal products in the EU, in the interest of patients and public health", said Guido Rasi, EMA's Executive Director. "I would like to thank all EU institutions and external stakeholders who have publicly endorsed our policies, as well as our staff who have been defending our approach to transparency for the past eight years".

The Court of Justice reiterated the principle of the widest possible public access to documents held by Union institutions, bodies, offices and agencies. An exception to that principle may be applied for the protection of commercial interests only if it is proven by the marketing authorisation holder/applicant that the disclosure of documents would pose the risk of a concrete harm to the commercial interests of the persons concerned. The Court of Justice agreed with EMA that such harm was not established in respect of the disclosure of the clinical study and toxicology reports at stake. The judges confirmed that transparency must be the rule and exceptions must be applied and construed narrowly.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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[1] Cases C-175/18 P, *PTC Therapeutics International v EMA*, and C-178/18 P, *MSD Animal Health Innovation and Intervet international v EMA.*