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Press release

General Court confirms EMA approach to transparency

Three rulings clarify the scope of commercial confidentiality with regard to authorised medicines

The General Court delivered today three landmark rulings for the European Medicines Agency (EMA), upholding EMA's decisions to release documents requested in accordance with Regulation (EC) No 1049/2001, the so-called "Transparency Regulation".

This is the first time that the Court of Justice of the European Union has had the opportunity to pronounce itself on the application of the Transparency Regulation to documents held by EMA. "We are very pleased that the General Court affirmed that the information contained in these documents cannot be considered commercially confidential in its entirety", explained Stefano Marino, EMA's Head of Legal Department. "We understand that with these rulings the General Court endorses our implementation of the Transparency Regulation that focuses on the interest of patients and public health".

The judgments concern Case T-235/15, *Pari Pharma v EMA*, in relation to the disclosure of similarity and superiority reports on an orphan medicine, prepared by the Committee for Medicinal Products for Human use (CHMP); Case T-718/15, *PTC Therapeutics International v EMA*, on the disclosure of a clinical study report; and Case T-729/15, *MSD Animal Health Innovation and Intervet international*, regarding five toxicology study reports for a veterinary medicine. In all three cases, the pharmaceutical companies challenged EMA's decision to release the concerned documents in accordance with the Transparency Regulation and EMA's 2010 policy on access to documents (Policy 0043).

The General Court noted that the companies failed to give any concrete evidence of how the release of the contested documents would undermine their commercial interests, and therefore it rejected their claims.

Based on the guidance issued today by the General Court, the Agency will continue to diligently assess each individual request for access to documents submitted under the Transparency Regulation and in accordance with its policy on access to documents.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 8427 **Facsimile** +44 (0)20 3660 5555
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

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

Contact our press officers

Tel. +44 (0)20 3660 8427
E-mail: press@ema.europa.eu
Follow us on Twitter @EMA_News