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Press release

New judicial decisions at odds with EMA's efforts to allow access to documents on medicines

EMA appeals interim measures

The European Medicines Agency (EMA) has appealed two interim orders by the President of the General Court of the European Union (EU) to suspend the release of documents requested by third parties under Regulation (EC) no. 1049/2001, the so-called "Transparency Regulation". The first order blocked the release of a clinical study report for Translarna, a centrally authorised medicine for the treatment of Duchenne's muscular dystrophy, until a final ruling is given by the General Court. EMA was planning to provide access to the clinical study report in response to an access to documents request, with appropriate redactions in accordance with the Regulation.

The second order, issued at the same time, blocked the release of three toxicity studies for Bravecto, a veterinary medicine used to treat flea and tick infestations in dogs and cats.

The interim rulings were made as part of court cases brought by PTC Therapeutics and Intervet respectively, to stop EMA's release of the documents in question.

Both companies argue that release of the requested documents would infringe their right to protect commercially confidential information contained in their dossiers. They are challenging two distinct Agency decisions to grant access to non-clinical and clinical information (including clinical study reports) previously submitted by companies as part of their marketing authorisation applications. In EMA's view, these decisions are fully consistent with the Transparency Regulation.

"Our approach to transparency has been welcomed by many of our stakeholders and these court cases are a good opportunity to test our rules on making available to the general public the documents on which EMA's scientific opinions on medicines are based," said Stefano Marino, EMA's Head of Legal Department. "Our position that clinical reports are not confidential *per se* was confirmed by the adoption of the recent Regulation on clinical trials. They may contain some residual commercially confidential information which should be redacted. However, a sort of "blanket" protection from disclosure for documents supporting an authorisation for a medicine seems neither consistent with the legislation nor advocated by our stakeholders, including an overwhelming majority of pharmaceutical companies. We will welcome a clear indication on this point from the Court of Justice."

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The Agency's access to documents policy entered into force in 2010. It gives the public the opportunity to obtain documents containing information about authorised medicinal products under the terms of the Transparency Regulation. The Regulation is the EU's central instrument to achieve transparency, which is indispensable for increasing citizens' understanding of EU decision-making and enhancing their confidence in the institutions.

Although the Agency's approach to access to documents has been challenged previously, the Court of Justice has never released a judgment on the merits of those cases. In the past, similar orders were set aside by the Court of Justice and the marketing authorisation holders then withdrew the main cases. The latest cases are an opportunity to receive clarity from the Court of Justice as to whether EMA's approach is correct or not and to eliminate operational uncertainties for the Agency or the stakeholders using its system.

These two interim rulings come as the Agency is preparing for the release of the first clinical study reports under its ground-breaking policy on the proactive release of clinical study reports, planned for later this year.

In the development of this new policy over the last four years, the Agency extensively consulted stakeholders from academia, patient and healthcare professional organisations and the pharmaceutical industry, as well as the European Ombudsman and the European Data Protection Supervisor, to take into account their views and concerns, particularly on the protection of personal data and commercially confidential information.

The two appeals filed by the Agency are in line with its continued efforts to secure transparency on authorised medicinal products in the EU and on the scientific reasons supporting their approval, in the interest of patients and public health.

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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