EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 April 2013
EMA/271410/2013
Press Office

**Press release**

# European Medicines Agency receives interim decisions of the General Court of the EU on access to clinical and non-clinical information

The European Medicines Agency (EMA) has been ordered by the General Court of the European Union not to provide documents as part of two access-to-documents requests until a final ruling is given by the Court. These interim rulings were made as part of court cases brought by two pharmaceutical companies, AbbVie and InterMune. The companies are challenging the Agency's decisions to grant access to non-clinical and clinical information (including clinical study reports) submitted by companies as part of marketing-authorisation applications in accordance with its 2010 access-to-documents policy.

While the Agency welcomes the opportunity for legal clarification of the concept of commercially confidential information, it notes with regret the decisions of the President of the General Court to grant interim relief to AbbVie and InterMune and to order the EMA not to release the concerned documents until a final judgement in the main cases is made.

The EMA is considering whether to appeal the interim decisions.

The EMA remains committed to transparency and openness of information to meet the legitimate public interests to enable scrutiny of the Agency's recommendations on medicines.

Pending the outcome of the final judgement on the main cases, the EMA will continue with its policy to grant access to documents. Requests for access to documents similar to those contested by AbbVie and InterMune will be considered on a case-by-case basis in the light of the Court Orders. Since November 2010, the Agency has released over 1.9 million pages in response to such requests. This is the first time that the policy has been legally challenged.

Since the two pharmaceutical companies filed these legal actions, the EMA has received more than 30 statements of support from various stakeholders, including the European Ombudsman, national competent authorities, members of the Agency's Management Board, Members of the European Parliament, academic institutions, non-governmental organisations, citizens' initiatives and scientific journals, some of whom have also applied to formally intervene in defence of the EMA at the Court.

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**Process toward proactive publication of clinical-trial data**

In 2012, the EMA started a process towards proactive publication of data from clinical trials supporting the authorisation of medicines once a marketing-authorisation decision has been taken. The Agency will continue the process of drafting its policy on proactive publication of clinical-trial data and will publish today the final advice from the five advisory groups which were set up to inform the Agency on specific aspects of the policy.

## 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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