



Reports of Cases

Order of the General Court (Second Chamber) of 8 March 2012 — Octapharma Pharmazeutika v EMA

(Case T-573/10)

(Medicinal products for human use — Changes to a plasma master file (PMF) — Fees payable to the EMA — Act with adverse effects — Measure merely confirmatory — Manifest inadmissibility)

1. *Actions for annulment — Actionable measures — Concept — Measures producing binding legal effects — Measures altering the applicant's legal situation — Administrative validation concerning payments due to the European Medicines Agency — Not included (Art. 263 TFEU; Council Regulation No 297/95, Art. 10(1)) (see paras 32-35)*
2. *Actions for annulment — Actionable measures — Concept — Measures producing binding legal effects — Measures altering the applicant's legal situation — EMA invoice establishing the exact amounts due for processing applications for amendment of the terms of a marketing authorisation and fixing the due date — Email from the agency rejecting a request to reduce the fees — Included (Art. 263 TFEU; Commission Regulation No 2343/2002, Arts 53(2) and (3), and 57(1)) (see paras 37-45, 51)*
3. *Procedure — Time limit for instituting proceedings — Claim barred by lapse of time — Excusable error — Concept — No action by reason of an email from the EMA informing the person concerned of the procedures for bringing an application for reduction of a debt due to the EMA — Not included (Art. 263, sixth para., TFEU) (see paras 47-49)*
4. *Actions for annulment — Action against a decision confirming an earlier decision not challenged within the time limits — Inadmissibility — Meaning of confirmatory decision — Decision recalling the legal basis of an earlier decision and reacting to a new argument submitted well after the expiry of the time limit for bringing an action against the earlier decision — Included (Art. 263 TFEU) (see paras 54-60)*

Re:

APPLICATION for annulment of the letter of 21 October 2010 (EMA/643425/2010) by which the European Medicines Agency (EMA) refused to repay to the applicant the sum of EUR 180 700 corresponding to the difference between, on the one hand, the sum the applicant paid to it in respect

of fees for the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products and, on the other hand, the sum which the applicant maintains it should have paid.

Operative part

1. The action is dismissed.
2. Octapharma Pharmazeutika Produktionsgesellschaft mbH is ordered to pay the costs.