

Change in the procedure for payment of application fees and fees for clinical trials

From 1.6.07 there will be a change in the procedure for payment of fees regarding regulatory procedures and clinical trials to the Norwegian Medicines Agency. The Agency will as of this date invoice these fees in conjunction with the submission of the application.

The following information will be given on the invoice: the name of medicinal product, the EU-procedure number/variation number/EudraCT number and the Agency's reference number. Each invoice corresponds to a single reference number, and the sender of the application will be invoiced. For clinical trials the invoice will be sent to those signing the EudraCT-form. As an application is not considered complete until the fee has been paid, it will not be finalised until payment is confirmed by the Agency's accounting department. For clinical trials the fee must be paid within 30 days after the study has been found valid.

All regulatory procedures for the following products will be affected; human and veterinary medicinal products, radiopharmaceuticals, natural remedies, chemical disinfectants, parallel import as well as applications for clinical trials. Studies not sponsored by pharmaceutical companies are still exempted from payment of fee.

Applications for which a fee already has been paid will be handled through the existing payment procedure.

The new procedure is founded on the updated regulations for medicinal products and clinical trials.

Norwegian Medicines Agency, May 2007.