THE SWEDISH MEDICAL PRODUCTS AGENCY

Clinical trials – Licences Maria Lüttgen/is

Decision

Date: 8 August 2014 EU no. 2011-006130-16

Ref. 5.1-2014-43006

Dr Veronica Murray Karolinska Institutet Danderyd Hospital 182 88 Stockholm

Permission for clinical pharmaceutical study

Clinical study of Oxatin (fluoxetine) (EFFECTS2012)

You have applied for permission to carry out a clinical pharmaceutical study.

Pursuant to § 14 of the Swedish Pharmaceuticals Act (1992:859), the Swedish Medical Products Agency grants permission to carry out the clinical pharmaceutical study.

In accordance with LVFS 2011:19, a decision from the Ethical Review Board should be sent to the Swedish Medical Products Agency no later than 15 days from the day on which the sponsor receives notice of the decision.

On behalf of the Swedish Medical Products Agency

Maria Lüttgen Specialist Physician

This decision document is not signed. This does not affect the validity of the decision.

Translated by

Språkservice

Reference: NKZ70

Malmö, Sweden: 20170920

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