STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 6

MANUFACTURE AND IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS

Application for manufacturing authorisation

38.—(1) An application for the grant of a manufacturing authorisation shall be—

(a) made to the licensing authority;

(b) in writing; and

(c) signed by or on behalf of the applicant.

(2) Every application for the grant of a manufacturing authorisation shall specify which, if any, of the standard provisions referred to in regulation 40(4) it is desired shall be excluded or modified in relation to the grant of the authorisation.

(3) Every application for the grant of a manufacturing authorisation shall be accompanied by—

(a) the particulars specified in Schedule 6 to these regulations; and

(b) any fee which may be payable in connection with that application under the Medicines (Products for Human Use—Fees) Regulations 1995(**1**).

(4) The application and any accompanying material shall be supplied to the licensing authority in the English language.

(**1**) S.I. 1995/1116.