STATUTORY RULES OF NORTHERN IRELAND

2012 No. 134

The Medicines (Products for Human Use) (Fees) Regulations 2012

PART 2

Capital Fees for Pre-Application Meetings

Interpretation of Part 2

3. In this Part—

"EU marketing authorization" means—

(a) a United Kingdom marketing authorization granted by the licensing authority under the Marketing Authorisation Regulations;

(b) a marketing authorization granted by the competent authority of an EEA State other than the United Kingdom in accordance with the 2001 Directive; or

(c) a European Union marketing authorization; and

"relevant medicinal product" means a medicinal product for human use to which the provisions of the 2001 Directive apply.