
STATUTORY RULES OF NORTHERN IRELAND

2012 No. 134

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

PART 4

Capital Fees for Assistance in Obtaining
Marketing Authorizations in Other EEA States

Meaning of “set of applications”

- 15.** For the purposes of this Part, a “set of applications” means—
- (a) a number of applications to the licensing authority for regulatory assistance in connection with obtaining recognition according to the procedure laid down in Title III, Chapter 4 of the 2001 Directive of a single United Kingdom marketing authorization in other EEA States, but only if all the applications relate to applications for marketing authorizations in other EEA States that have the same 90 day assessment period for the purposes of Article 28(4) of the 2001 Directive; or
 - (b) a number of applications to competent authorities of other EEA States for marketing authorizations relating to a single United Kingdom marketing authorization, but only if all the applications have the same 90 day assessment period for the purposes of Article 28(4) of the 2001 Directive.