STATUTORY RULES OF NORTHERN IRELAND

2014 No. 324

The Human Medicines (Amendment) (No. 2) Regulations 2014

Amendment of regulation 75

14.—(1) Regulation 75 (obligation to provide information relating to safety etc) is amended as follows.

(2) In paragraph (2), after the first occurrence of the word "holder" insert "of a UK marketing authorisation".

(3) After paragraph (2) insert—

"(2A) The holder of a parallel import licence must, in particular, provide the licensing authority with—

(a) information about any prohibition or restriction imposed in relation to the product to which the licence relates by the competent authority of any country in which the product is on the market; and

(b) other information that the holder considers might influence the evaluation of the benefits and risks of the product."

(4) In paragraph (3), for "or (2)" substitute "to (2A)".

(5) After paragraph (4) insert—

"(4A) The licensing authority may require the holder of a parallel import licence to provide further information specified by the licensing authority."

(6) In paragraph (5) after "(4)" insert "or (4A)".

(7) In paragraph (6) for "or (4)" substitute ", (4) or (4A)".

(8) In paragraph (8) for "(4) or " substitute "(4), (4A) or".