STATUTORY RULES OF NORTHERN IRELAND

2014 No. 324

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

Insertion of regulation 57A

7. After regulation 57 (obligation to update information supplied in connection with application for UK marketing authorisation) insert—

"**Obligation to update information supplied in connection with parallel import licence application**

57A.—(1) The applicant for a parallel import licence must update information supplied in accordance with Schedule 8A (material to accompany an application for a parallel import licence) in connection with the application.

(2) The applicant must update information supplied in connection with the application to include any further information that is relevant to the evaluation of the safety, quality or efficacy of the product concerned.

(3) Updated information within paragraphs (1) or (2) must be provided as soon as is reasonably practicable after the applicant becomes aware of it."