STATUTORY RULES OF NORTHERN IRELAND

2012 No. 134

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

PART 15

Consequential Amendments

Amendment of the Medicines for Human Use (Clinical Trials) Regulations 2004

55.—(1) The Medicines for Human Use (Clinical Trials) Regulations 2004(**1**) are amended as follows.

(2) In regulation—

(a) 17(2)(b)(ii) (request for authorisation to conduct a clinical trial),

(b) 24(10) (amendments by the sponsor),

(c) 38(3)(b) (application for manufacturing authorisation),

(d) 44(8) (variation of manufacturing authorisation),

for "Medicines (Products for Human Use) (Fees) Regulations 2010" substitute "Medicines (Products for Human Use) (Fees) Regulations 2012".

Amendment of the Homoeopathic Regulations

56. The Homoeopathic Regulations are amended by omitting the following definitions in regulation 1(2)(**2**) (citation, commencement and interpretation)—

(a) "administrative variation",

(b) "the Board",

(c) "concerned member State",

(d) "set of applications", and

(e) "standard variation".

(**1**) S.I. 2004/1031; relevant amendments are made by S.I. 2006/1928, 2010/551.

(**2**) The definition of "administrative variation" was inserted by S.I. 1998/574. The definitions of "concerned member state" and "set of applications" were inserted by S.I. 2005/2753. The definition of "standard variation" was inserted by S.I. 1998/574 and amended by S.I. 2001/795.