
STATUTORY RULES OF NORTHERN IRELAND

2014 No. 324

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

Amendment of Schedule 27

28.—(1) Schedule 27 (package leaflets) is amended as follows

(2) In paragraph 13 omit the word “safety”.

(3) For paragraph 14 substitute—

“**14.** A standardised text relating to adverse event reporting in accordance with the third sub-paragraph of Article 59(1) of the 2001 Directive.”