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STATUTORY INSTRUMENTS

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**2012 No. 1916**

**The Human Medicines Regulations 2012**

**PART 14**

**Advertising**

**CHAPTER 2**

**Requirements relating to advertising**

*Advertising to persons qualified to prescribe or supply etc*

**Free samples for persons qualified to prescribe or supply medicinal products**

**298.**—(1) A person (“the supplier”) may not supply a free sample of a medicinal product to another person (“the recipient”) unless the following conditions are met.

- (2) Condition A is that the recipient—
  - (a) is qualified to prescribe medicinal products; and
  - (b) receives the sample for the purpose of acquiring experience in dealing with the product in question.
- (3) Condition B is that the sample is supplied to the recipient—
  - (a) on an exceptional basis; and
  - (b) in response to a request from, and signed and dated by, the recipient.
- (4) Condition C is that, taking the year in which the sample is supplied as a whole, only a limited number of samples of the product in question are supplied to the recipient in that year.
- (5) Condition D is that the sample—
  - (a) is no larger than the smallest presentation of the product that is available for sale in the United Kingdom;
  - (b) is marked “free medical sample – not for resale” or bears a similar description; and
  - (c) is accompanied by a copy of the summary of the product characteristics.
- (6) Condition E is that the sample does not contain—
  - (a) a substance which is listed in any of Schedules I, II or IV to the Narcotic Drugs Convention (where the product is not a preparation listed in Schedule III to that Convention); or
  - (b) a substance which is listed in any of Schedules I to IV to the Psychotropic Substances Convention (where the product is not a preparation which may be exempted from measures of control in accordance with paragraphs 2 and 3 of article 3 of that Convention).
- (7) Condition F is that the supplier maintains an adequate system of control and accountability in relation to the supply of free samples.