STATUTORY INSTRUMENTS

2015 No. 895

The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015

Exception for medicines indicated for the treatment of persons aged under 18

5.—(1) This regulation applies to the sale of a nicotine inhaling product which—

(a) is an authorised medicinal product; and

(b) is indicated for the treatment of persons of the age of the person to whom the product is sold.

(2) For the purposes of this regulation—

(a) a product is indicated for the treatment of persons of a particular age if it is described as such in the summary of the product characteristics for the product in accordance with paragraph 27 of Schedule 8 to the Human Medicines Regulations 2012 (summary of the product characteristics) or Article 11 of Directive 2001/83/EC of the European Parliament and of the Council of 6th November 2001 on the Community code relating to medicinal products for human use (**1**);

(b) "the summary of the product characteristics" is to be construed in accordance with Article 11 of Directive 2001/83/EC;

(c) a medicinal product is "authorised" if one of the following is in force for the product—

(i) a marketing authorisation; or

(ii) a parallel import licence.

(**1**) Directive 2001/83/EC (OJNo. L 311, 28.11.2001), as amended by Directive 2012/26/EU (OJ No. L 299, 27.10. 2012, p.1).