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DRAFT STATUTORY RULES OF NORTHERN IRELAND

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**2021 No.**

**The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations (Northern Ireland) 2021**

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

- 6.—(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<sup>(1)</sup>;
  - (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.

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(1) [Directive 2001/83/EC](#) (OJ No. L311, 28.11.2001) as amended by [Directive 2012/26/EU](#) (OJ No. L299, 27.10.2012, p.1.)