STATUTORY RULES OF NORTHERN IRELAND

2021 No. 330

PUBLIC HEALTH

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

Laid before the Assembly in draft

Made - - - - 6th December 2021

Coming into operation - 1st February 2022

The Department of Health makes the following Regulations, in exercise of the powers conferred by sections 1(1) and (6), 3(2) and 18(2) of the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016(**a**).

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations (Northern Ireland) 2021 and shall come into operation on 1st February 2022.

(2) In these Regulations—

"marketing authorisation" has the meaning given by regulation 8(1) of the Human Medicines Regulations 2012(**b**);

"medical device" has the meaning given by regulation 2(1) of the Medical Devices Regulations 2002(**c**);

"medicinal product" has the meaning given by regulation 2(1) of the Human Medicines Regulations 2012;

"nicotine cartridge" means a cartridge which—

(a) contains a substance which is not tobacco(**d**) but consists of, or contains, nicotine, and

(b) is intended to form part of a nicotine inhaling device;

"nicotine inhaling device" means a device which—

(a) is intended to enable nicotine to be inhaled through a mouth piece (regardless of whether the device is also intended to enable any other substance to be inhaled through a mouth piece), but

(b) is not tobacco, cigarette papers or a device intended to be used for the consumption of lit tobacco;

(**a**) 2016 c.26.
(**b**) S.I. 2012/1916.
(**c**) S.I. 2006/618. Relevant amendment was made by S.I. 2008/2936.
(**d**) See the definition of "tobacco" in Article 7 of the Health and Personal Social Services (Northern Ireland) Order 1978 (S.I. 1978/1907 (N.I. 26)).

"nicotine inhaling product" means a nicotine inhaling device, nicotine cartridge or nicotine refill substance;

"nicotine refill substance" means a substance which—

(a) is not tobacco but consists of, or contains, nicotine, and

(b) is intended to be used to refill a nicotine inhaling device;

"parallel import licence" has the meaning given by regulation 48(2) of the Human Medicines Regulations 2012;

"prescription only medicine" has the meaning given by regulation 8(1) of the Human Medicines Regulations 2012.

Proxy purchase of nicotine products

2.—(1) Article 4A of the Health and Personal Social Services (Northern Ireland) Order 1978(**a**) (purchase of tobacco on behalf of persons under 18) is amended in accordance with paragraphs (2) and (3).

(2) In the heading, after "tobacco" insert "or nicotine products".

(3) In paragraph (1), for "or cigarette papers" substitute ", cigarette papers or a relevant nicotine product".

Interpretation of "relevant nicotine product"

3. Article 7 of the Health and Personal Social Services (Northern Ireland) Order 1978 (interpretation) is amended by inserting at the appropriate place—

> ""relevant nicotine product" means a nicotine product within the meaning of section 7 of the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016 the sale of which to persons aged under 18 is for the time being prohibited by regulations under section 1(1) of that Act;".

Prohibition of sale of nicotine inhaling products to persons aged under 18

4. The sale of nicotine inhaling products to persons aged under 18 is prohibited, except where regulation 5 or 6 applies.

Exception for sales of medicines and medical devices in accordance with a prescription etc.

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

(a) the nicotine inhaling product is a medicinal product or a medical device; and

(b) the circumstances of the sale are such that it would be permitted under Part 12 of the Human Medicines Regulations 2012 (dealing with medicinal products) if the nicotine inhaling product were a prescription only medicine.

(2) For the purposes of paragraph (1)(b), Part 12 of the Human Medicines Regulations 2012 is to be read as if regulation 244 (exemption in cases involving another's default) were omitted.

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.

(**a**) S.I. 1978/1907 (N.I. 26), Article 4A was inserted by the Tobacco Retailers Act (Northern Ireland) 2014 (2014 c.4).

(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(**a**);

(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.

Sealed with the Official Seal of the Department of Health on 6th December 2021.

L.S.

Elizabeth Redmond
A senior officer of the
Department of Health

(**a**) 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.)

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, made under section 1 of the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016, contain provisions to make it an offence to sell nicotine inhaling products to persons aged under 18 and for an adult to purchase nicotine inhaling products on behalf of a person aged under 18.

Regulation 2 amends Article 4A of the Health and Personal Social Services (Northern Ireland) Order 1978. Under that Article, it is an offence for an adult to purchase tobacco or cigarette papers on behalf of someone under 18. That Article is amended so that it is also an offence for an adult to purchase relevant nicotine products on behalf of someone under 18.

Regulation 3 amends Article 7 of the Health and Personal Social Services (Northern Ireland) Order 1978 to include a definition of a relevant nicotine product.

Regulation 4 prohibits the sale of nicotine inhaling products to someone under the age of 18.

Regulation 5 provides for an exception to the prohibition in regulation 4 if the product is licenced as either a medicinal product or a medical device and is sold by prescription.

Regulation 6 provides for an exception to the prohibition in regulation 4 if the product is an authorised medicinal product which has been indicated for the treatment of persons that are of the age of the person the product is sold to.

© Crown copyright 2021

Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Jeff James, Controller of Her Majesty's Stationery Office being the Government Printer for Northern Ireland and the Officer appointed to print Acts of the Northern Ireland Assembly.

£4.90

http://www.legislation.gov.uk/id/nisr/2021/330

ISBN 978-0-33-801781-9

9 780338 017819