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DRAFT STATUTORY INSTRUMENTS

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**2015 No.**

**PUBLIC HEALTH, ENGLAND AND WALES**

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

*Made* - - - - *\*\*\**

*Coming into force in accordance with regulation 1*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 92(1), (6) and (7), 93(8) and 135(2) of the Children and Families Act 2014(a).

In accordance with section 135(6) of that Act, a draft of this instrument has been laid before and approved by resolution of each House of Parliament.

In accordance with section 92(8) of that Act, the Secretary of State makes this instrument with the consent of the Welsh Ministers.

**Citation, commencement and interpretation**

**1.**—(1) These Regulations may be cited as the Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015.

(2) Regulations 1 and 2 come into force on the day after the day on which these Regulations are made.

(3) Regulations 3 to 7 come into force on 1st October 2015.

(4) 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 but consists of, or contains, nicotine(d), and

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(a) 2014 c.6. See section 92(12) for the meaning of “specified”.

(b) S.I. 2012/1916. Relevant amendments were made by S.I. 2013/235, 1855, 2593, 2014/490, 1878.

(c) S.I. 2002/618. Relevant amendments were made by S.I. 2008/2936.

(d) See the definition of “tobacco” at section 92(12) of the Children and Families Act 2014.

(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;

“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) Section 91 of the Children and Families Act 2014 (purchase of tobacco etc. on behalf of persons under 18) is amended in accordance with paragraphs (2) to (4).

(2) In the heading, before “etc.” insert “, nicotine products”.

(3) In subsection (1), for “or cigarette papers” substitute “, cigarette papers or a relevant nicotine product”.

(4) After subsection (7) add—

“(8) In this section “relevant nicotine product” means a nicotine product within the meaning of section 92 the sale of which at the same time and in the same circumstances to the individual aged under 18 would be prohibited by regulations for the time being in force under subsection (1) of that section.”.

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

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

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

**4.**—(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 (dealings 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**

**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 (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.

### **Amendment of Schedule 3 to the Regulatory Enforcement and Sanctions Act 2008**

6. In Schedule 3(b) to the Regulatory Enforcement and Sanctions Act 2008(c) (enactments specified for the purposes of Part 1), at the appropriate place insert—

“Children and Families Act 2014 (c.6), section 92”.

### **Review**

- 7.—(1) The Secretary of State must from time to time—
- (a) carry out a review of regulations 3 to 5 including the definitions of “nicotine cartridge”, “nicotine inhaling device”, “nicotine inhaling product” and “nicotine refill substance” in regulation 1(4),
  - (b) set out the conclusions of the review in a report, and
  - (c) publish the report.
- (2) The report must in particular—
- (a) set out the objectives intended to be achieved by the regulatory system established by those regulations,
  - (b) assess the extent to which those objectives are achieved, and
  - (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.
- (3) The first report under this regulation must be published before the end of the period of five years beginning with 1st October 2015.
- (4) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

Signed by authority of the Secretary of State

Address Date	<i>Name</i> Parliamentary Under Secretary of State Department of Health
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- (a) Directive 2001/83/EC (OJ No. L 311, 28.11.2001), as amended by Directive 2012/26/EU (OJ No. L 299, 27.10.2012, p.1).
  - (b) Schedule 3 was amended by Part 4 of Schedule 22 to the Marine and Coastal Access Act 2009 (c.23), paragraphs 97 and 99 of Schedule 26 and Part 1 of Schedule 27 to the Equality Act 2010 (c. 15) (as amended by SI 2010/2279, Schedule 1, paragraph 6 and Schedule 2), paragraph 130 of Part 2 of Schedule 7 to the Charities Act 2011 (c. 25), paragraph 4(1) and (2) of Schedule 6 and Part 1 of Schedule 8 to S.I. 2010/2960, section 19(2) of the Scrap Metal Dealers Act 2013 (c.10), paragraphs 12 and 13 of Part 1 of the Schedule to S.I. 2013/1575, regulation 2 of S.I. 2013/2215 and paragraph 10 of Schedule 4 to the Mobile Homes (Wales) Act 2013 (anaw 6).
  - (c) 2008 c.13.

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations, made under Part 5 of the Children and Families Act 2014, contain provisions to make it an offence to sell certain 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 section 91 of the Children and Families Act 2014. Under that section it is an offence for an adult to purchase tobacco or cigarette papers on behalf of someone under 18. That section 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 prohibits the sale of nicotine inhaling products to someone under the age of 18.

Regulation 4 provides for an exception to the prohibition in regulation 3 if the product is licenced as either a medicinal product or a medical device and is sold by prescription.

Regulation 5 provides for an exception to the prohibition in regulation 3 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.

Regulation 6 includes section 92 of the Children and Families Act 2014 in the list of enactments in Schedule 3 to the Regulatory Enforcement and Sanctions Act 2008. That Schedule sets out the enactments which contain the functions of local authorities about which the Local Better Regulations Office (now the Better Regulation Delivery Office), established under that Act, may provide guidance on, or financial assistance in respect of.

Regulation 7 provides for a review of the prohibition on the sale of nicotine products to persons under 18.

An Impact Assessment has been prepared for these Regulations and is published with the Explanatory Memorandum alongside the instrument on [www.legislation.gov.uk](http://www.legislation.gov.uk).

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