

STATES OF JERSEY



DRAFT PROTECTION OF CHILDREN (NICOTINE INHALING PRODUCTS) (JERSEY) REGULATIONS 201-

**Lodged au Greffe on 11th March 2016
by the Minister for Health and Social Services**

STATES GREFFE



Jersey

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REPORT

1. Purpose

The purpose of the proposed Regulations under the Protection of Children (Restriction on Supply of Goods) (Jersey) Law 2009 is to restrict the sale of nicotine-inhaling products commonly known as electronic cigarettes or vaporisers to people under the age of 18. Such a restriction is proposed to protect under-18s from the unknown long-term health risks of such products, as well as from exposure to addictive nicotine.

2. Background

Electronic (e) cigarettes (also known as vaporisers) are often, although not always, designed to look like cigarettes. There are 3 main types –

- disposable products which cannot be recharged
- rechargeable products which come with replaceable pre-filled cartridges
- tank systems which come with a tank or reservoir which the user fills with liquid nicotine, and which are rechargeable.

The liquid in the device usually contains a variable amount of nicotine and may also contain flavourings. When the liquid is heated, it evaporates and delivers nicotine to the user in the form of vapour. Some nicotine vapour is delivered into the air as the smoker inhales.

E-cigarettes are not risk-free.

- Most, but not all, e-cigarettes also contain nicotine.
- Nicotine is an addictive drug that stimulates the nervous system, increasing the heart rate and blood pressure.
- Nicotine has been linked with causing harm to people with existing heart conditions, and can lead to impaired growth of babies during pregnancy (In this context, Nicotine Replacement Therapy is licensed for use and is the preferred source of nicotine to support stopping smoking, and is in the best interests for the health of mother and baby.) Any potential risks from nicotine within Nicotine Replacement Therapy should always be viewed in the context of the known harm caused by continuing to smoke.

Additionally, chemicals have been found in some of the available vaporising systems of e-cigarettes, many of which are known to cause different cancers.

In the absence of effective regulation, it is not possible to offer any assurance over the relative level of safety, quality and effectiveness across the growing range of available products. E-cigarettes are relatively new phenomena, and therefore the medium- and longer-term effects are not yet known.

Nationally, and internationally, there is a growing concern at indicators of increasing use of these products by under-18s. Although likely to be less harmful than using tobacco, the long-term health effects are largely unknown. The UK Parliament has recently agreed to restrict sale to under-18s, with this coming into force on 1st October 2015. The Minister for Health and Social Services would urgently like to follow suit.

The implementation of these future Regulations controlling nicotine-inhaling products would be consistent with meeting the [Tobacco Control Strategy \(2010 - 2015\)](#) key objective of protecting families and communities from tobacco-related harm. Nicotine is the active ingredient in tobacco, increasing heart rate and blood pressure, and stimulating the nervous system. Nicotine is an addictive substance and should not be supported for recreational use in under-18s. E-cigarettes are currently unregulated, leaving under-18s at risk.

Further future options to regulate the quality and efficacy of these products, currently included within the European Tobacco Products Directive and coming into force this year, are being considered by officers.

3. Summary of proposed Regulations

These Regulations will make it an offence to sell or supply a nicotine-inhaling product or their component parts to a person under the age of 18 years. The Regulations define the elements of what makes a nicotine-inhaling product and device, and sets out in what terms an offence for supply of such products is an offence. Further Regulations set out exemptions to supply to under-18s under aspects of the Medicines (Jersey) Law 1995. This ensures that under-18s would be able to access such products for the therapeutic treatment of nicotine addiction.

4. Summary

Given that nicotine is an addictive substance, and in the light of current questions over the long-term safety and health risks of e-cigarettes, it is the responsibility of the States of Jersey to protect children and young people from unknown future risks from these products. It is therefore proposed that these Regulations, to be made under the Protection of Children (Restriction on Supply of Goods) (Jersey) Law 2009, are approved to bring into effect a restriction of the sale of nicotine-inhaling products to under-18 year-olds.

5. Financial and manpower implications

The Protection of Children (Restriction on Supply of Goods) (Jersey) Law 2009 is enforced by Trading Standards. The Director has been engaged in the preparation of these draft Regulations, and will respond to enquiries and investigate complaints in line with other age-restricted products controlled under this Law. There are no additional financial or manpower implications arising.

Explanatory Note

These Regulations prohibit the supply of nicotine inhaling products (including “e-cigarettes”), and their component parts to persons under the age of 18 years.

Regulation 1 is an interpretation provision. In particular it defines “nicotine inhaling device” and its component parts comprising a “nicotine refill substance” and “nicotine cartridge”. A “nicotine inhaling product” is defined to mean any of these 3 things.

Regulation 2 prohibits the supply of a nicotine inhaling product to any person under the age of 18 years except where Regulation 3 or 4 applies. “Supply” is defined in Regulation 1 to include the act of selling and the act of making a gift. The effect of Article 4 of the Protection of Children (Restriction on Supply of Goods) (Jersey) Law 2009 is that a person who contravenes *Regulation 2* is guilty of an offence and liable to imprisonment for a maximum term of 12 months and to an unlimited fine.

Regulation 3 provides an exception to the prohibition in *Regulation 2* if the nicotine inhaling product is an authorized medicinal product which has been indicated for the treatment of persons that are of the age of the person to whom the nicotine inhaling product is supplied.

Regulation 4 provides for an exception to the prohibition in *Regulation 2* if the nicotine inhaling product is supplied in circumstances where, if it were a medicinal product specified in an Order under Article 57 of the Medicines (Jersey) Law 1995, it would be permitted under that Article. Article 57 prohibits retail sales or supplies of medicinal products without a prescription given by an “appropriate practitioner” except in circumstances set out in that Article or in an Order made under that Article. (The descriptions of persons who are “appropriate practitioners” are specified by Order under Article 57 and include doctors.)

Regulation 5 sets out the title of these Regulations and provides that they will come into force 7 days after the day they are made.



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Arrangement

Regulation

1	Interpretation	9
2	Prohibition on supply of nicotine inhaling products to children	10
3	Exception for supply of nicotine inhaling products indicated for the treatment of persons aged under 18.....	10
4	Exception for supply of nicotine inhaling products as if they were prescription only medicines	11
5	Citation and commencement	11



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DRAFT PROTECTION OF CHILDREN (NICOTINE INHALING PRODUCTS) (JERSEY) REGULATIONS 201-

Made [date to be inserted]
Coming into force [date to be inserted]

THE STATES, in pursuance of Article 2 of the Protection of Children (Restriction on Supply of Goods) (Jersey) Law 2009¹, have made the following Regulations –

1 Interpretation

In these Regulations –

“appropriate practitioner” means a person of a description or class specified by Order under Article 57(1)(b) of the Medicines Law;

“Medicines Law” means the Medicines (Jersey) Law 1995²;

“medical device” means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which –

- (a) is intended by the manufacturer to be used for human beings for the purpose of –
 - (i) diagnosis, prevention, monitoring, treatment or alleviation of disease,
 - (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
 - (iii) investigation, replacement or modification of the anatomy or of a physiological process, or
 - (iv) control of conception; and
- (b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means,

including devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately,

would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device;

“medicinal product” has the same meaning as in Article 2 of the Medicines Law;

“nicotine cartridge” means a cartridge which –

- (a) contains a substance which is not tobacco 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 ignited 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;

“prescription only medicine” means a medicinal product specified in an Order under Article 57(1)(a) of the Medicines Law;

“supply” includes the act of selling and the act of making a gift.

2 Prohibition on supply of nicotine inhaling products to children

The supply of any nicotine inhaling product to any person under the age of 18 years is prohibited except where Regulation 3 or 4 applies.

3 Exception for supply of nicotine inhaling products indicated for the treatment of persons aged under 18

- (1) Regulation 2 does not apply to the supply of a nicotine inhaling product which –
 - (a) is an authorized medicinal product; and
 - (b) is indicated for the treatment of persons of the age of the person to whom the product is supplied.
- (2) For the purposes of this Regulation –
 - (a) a medicinal product is “authorized” if a product licence granted for the purposes of Article 8 of the Medicines Law is in force which is applicable to it; and
 - (b) a nicotine inhaling product is indicated for the treatment of persons of a particular age if it is described as such –
 - (i) in the clinical particulars for the product in accordance with paragraph 9(d) of Schedule 1 to the Medicines (Applications

for Licences for Products for Human Use) (Jersey)
Order 1997³, or

(ii) in accordance with paragraph (4).

- (3) The reference to a “product licence” in paragraph (2)(a) includes a valid United Kingdom product licence or a valid marketing authorization which has effect as if it were a product licence in accordance with Article 7(2) of the Medicines Law.
- (4) Where a medicinal product is authorized by virtue of a product licence described in paragraph (3), a nicotine inhaling product is indicated for the treatment of persons of a particular age if it is described as such in accordance with Regulation 5(2)(a) of the Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015 of the United Kingdom.

4 Exception for supply of nicotine inhaling products as if they were prescription only medicines

Regulation 2 does not apply to supply 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 supply are such that, if the nicotine inhaling product were a prescription only medicine, its supply would be permitted under Article 57 of the Medicines Law (including any exemption under that Article).

5 Citation and commencement

These Regulations may be cited as the Protection of Children (Nicotine Inhaling Products) (Jersey) Regulations 201- and shall come into force 7 days after the day they are made.

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- ¹ *chapter 05.620*
² *chapter 20.625*
³ *chapter 20.625.20*