

Manufacturing, importing or selling vapes

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Tobacco and Related Products Regulations 2016 (TRPR)

The TRPR control the safety and quality of all vaping products and nicotine refill containers, as well as product information, labelling, presentation and advertising.

The TRPR refer to 'electronic cigarettes' (e-cigarettes) but for the purposes of this guide, this is replaced by 'vapes' or 'vaping products', which are now more commonly used terms.

Terminology used in the TRPR

Producer. This is a person who, in the course of business and for supply for consumption in the UK (or through the travel retail sector*) does any of the following:

- manufactures the product
- puts a name, trade mark or other distinguishing mark on the product
- imports the product into any part of the United Kingdom (UK)

Supplier. This is a person who, in the course of business, does any of the following:

- supplies the product for consumption in any part of the UK or through the travel retail sector*

- supplies the product with a view to it being supplied for consumption in any part of the UK or through the travel retail sector*
- offers or agrees to supply the product
- exposes or possesses the product for supply

[*An example of the 'travel retail sector' would be duty-free shops at airports.]

Product requirements

General product requirements

Regulation 36 of the TRPR sets out product requirements for those producing or supplying a vaping product or refill container, as follows.

Table showing general product requirements

| Type of product | Requirement |
|---|--|
| Liquid that contains nicotine (for retail sale) | Must be either: <ul style="list-style-type: none"> • in a dedicated refill container in a volume not exceeding 10 ml or • in a disposable vape, single-use cartridge or a tank in a volume not exceeding 2 ml |
| Tank capacity of a refillable vape | Must not exceed 2 ml |
| Liquid that contains nicotine in a vape or refill container (for retail sale) | Must: <ul style="list-style-type: none"> • be manufactured with high purity ingredients • not contain nicotine in excess of 20 mg per ml • not contain vitamins, colourings or certain prohibited additives • not contain substances other than those ingredients notified to the Medicines and Healthcare products Regulatory Agency (trace levels may be permitted). See 'MHRA notification scheme and reporting system' below • not include ingredients that pose a risk to human health |
| Vape | Must deliver a consistent dose of nicotine when used normally* |
| Vape or refill container | Must: <ul style="list-style-type: none"> • be child resistant, tamper evident (a type of packaging that makes it clear and obvious to the user when it has been interfered with) and protect against breakage and leakage • have a mechanism to allow for refilling without leakage (does not apply to disposables) |

[*Generally, 2 ml of nicotine liquid in a disposable vape is equivalent to a delivery dose of around 600 -

800 puffs. However, as manufacturers develop and refine their products, they are achieving a higher 'puff count' from the tank's legal maximum capacity. It is not advisable, therefore, to use the number of puffs displayed on labelling or any other promotional material as an indicator that the product is or is not legally compliant.]

Information and labelling requirements

Regulation 37 sets out product information and labelling requirements for those producing or supplying a vaping product or refill container, as follows.

Table showing information and labelling requirements

| Type of product | Requirement |
|---|---|
| Vape or refill container (unit packet) | <p>Must include a leaflet with the following information:</p> <ul style="list-style-type: none"> • instructions for storage and use • product is not recommended for use by young people and non-smokers • contra-indications (specific reasons why the product should not be used) • warnings for specific risk groups • possible adverse effects • addictiveness and toxicity • contact details for the producer |
| Vape or refill container (unit packet and any container pack) | <p>Must include:</p> <ul style="list-style-type: none"> • ingredients list • nicotine content and delivery per dose* • batch number • recommendation to keep out of the reach of children <p>Must carry the following health warning:</p> |
| Vape or refill container (unit packet and any container pack) | <p>'This product contains nicotine which is a highly addictive substance'</p> <p>Regulation 37 sets out how the health warning must appear on the surfaces of the product</p> |

[*Generally, 2 ml of nicotine liquid in a disposable vape is equivalent to a delivery dose of around 600 - 800 puffs. However, as manufacturers develop and refine their products, they are achieving a higher 'puff count' from the tank's legal maximum capacity. It is not advisable, therefore, to use the number of puffs displayed on labelling or any other promotional material as an indicator that the product is or is not legally compliant.]

Production presentation requirements

Regulation 38 sets out product presentation requirements for those producing or supplying a vaping product or refill container, as follows.

Table showing production presentation requirements

Type of product

Requirement

| | |
|---|--|
| Vape or refill container (unit packet and any container pack) | <p>Must not contain elements or features (including text, symbols, names and trade marks) that:</p> <ul style="list-style-type: none">• promote or encourage a product's use through creating a false impression about its characteristics, health effects, risks or emissions• suggest that a particular product is less harmful than others and/or has health and lifestyle benefits• refer to taste, smell or other additives• resemble a food or a cosmetic product• suggest that a particular product has environmental advantages, such as improved biodegradability |
| Vape or refill container (unit packet and any container pack presented for retail sale) | Must not contain offers such as printed vouchers, discounts, free distribution or two-for-one |

Advertising

The advertising of vapes is heavily restricted by Part 7 of the TRPR and you may not, in the course of your business, do any of the following:

- publish or arrange the publication of a vape advertisement in a newspaper, periodical or magazine*
- offer for sale, sell or make available to the public a newspaper, periodical or magazine that contains a vape advertisement*
- include or arrange to include a vape advertisement in what is known as an 'information society service'. This broadly covers online services such as apps, search engines, social media platforms, content streaming services and online games. There is an exception for services exclusively for the trade
- undertake product placement of vapes on television

[*There are exceptions that apply to trade publications and those publications not destined for the market in Great Britain (GB).]

The advertising of vapes and refill containers in on-demand programme services is prohibited.

Non-nicotine vapes and 0% nicotine e-liquids

The TRPR do not apply to non-nicotine vapes and 0% nicotine e-liquids. However, these products are regulated by the General Product Safety Regulations 2005 (GPSR).

These Regulations place a duty on producers (for example, manufacturers or those importing goods into GB) and distributors* (traders in the supply chain whose activities do not affect the safety of a product - for example, wholesalers and retailers) to supply non-nicotine vaping products that are safe for consumers when used in a normal or reasonably foreseeable way.

[*Similar to 'suppliers' as the TRPR defines them.]

See the '[General product safety: producers](#)' and '[General product safety: distributors](#)' guides for more information on these Regulations.

The following are all important factors when deciding whether a non-nicotine vaping product is safe:

- the characteristics of the product (how it is made, packaging and any instructions for assembly)
- the effect of the product on other products it is used with
- its presentation (labelling, warnings and any instructions for use and disposal)
- the types of consumers using the product

There are a significant number of illegal vaping products that claim to be nicotine-free when, in fact, they contain nicotine, often at higher strengths and a greater capacity than what is legally allowed.

As these vaping products claim not to contain nicotine and do not require notification to the Medicines and Healthcare products Regulatory Agency (MHRA), they will not appear on the MHRA ECIG notified products list (see below for more information).

Distributors and 'due care'

Distributors have a specific obligation to act with 'due care' under the GPSR to help ensure that safety requirements are complied with, and it is an offence under the Regulations if they fail to do so. This means that distributors:

- must not expose or possess for supply, or offer or agree to supply, or supply a vaping product to anyone if they know, or ought to know, that it is a dangerous product
- must, within the limitations of their business, play a part in monitoring the safety of vaping products placed on the market. This is done by keeping and producing documentation that will help to trace the origins of the product and by passing on information about any risks the product poses to the producer (generally the manufacturer or importer) or to Trading Standards for further investigation

It is best practice for suppliers to exercise all due diligence on producers that provide them with vaping products, so that they can satisfy themselves that producers are operating legally, and that the products are legally compliant and labelled accurately.

MHRA notification scheme and reporting system

The Medicines and Healthcare products Regulatory Agency (MHRA) is the competent authority for the UK's notification scheme for nicotine-containing vaping products. Products cannot be supplied legally until the notification has been published.

You can check the [MHRA notified products list](#) through the search tool on its website.

Suspected problems (adverse incidents) with a vaping product can be reported through the MHRA [Yellow Card](#) system.

Producers

Six months before the product is placed on the market, you, as a producer of nicotine-containing vapes and refill containers, must submit information about your products to the MHRA using the MHRA

submission portal. This includes:

- ingredients and emissions information
- toxicology data
- information on the nicotine dose and uptake when used normally
- a description of the components of the product
- a description of the production process

You must also notify the MHRA of the withdrawal of a product from the market. The MHRA makes the information you submit publicly available through its website.

There is also an annual reporting requirement for manufacturers and importers, which must submit data on sales volumes, preferences by consumer groups, methods of sale of the vaping products and summaries of any market surveys conducted.

If you import or re-brand products, you must find out from the business that provided you with the products whether they have made a product notification to the MHRA. If they have done so, you do not need to submit another one.

As a producer, you must establish and maintain a system for collecting information about all suspected adverse effects of the vaping product. You must inform the MHRA about:

- suspected risks to human health and safety
- any corrective action taken
- results of corrective action taken

Suppliers

If you are a supplier, you should ensure, before you purchase these products, that they have been properly notified and not subsequently withdrawn. You can do this by checking the list of submitted vaping products on the MHRA website or, if you cannot find them on the list, you should ask the producer to confirm that they comply with the requirements of the TRPR and have been notified to the MHRA. Vaping products that have not been notified, or have been withdrawn, cannot be supplied and may be seized by Trading Standards.

CE / UKCA marking

If you as a manufacturer, or your authorised representative, produce vaping products that are charged from the mains electricity supply, they must carry the [CE](#) and/or [UKCA](#) mark.



If you are based in the UK and import products from a country outside the UK to be placed on the GB market, you must ensure that the manufacturer, or their authorised representative, has complied with their CE / UKCA marking obligations.

Distributors* must verify that the products carry the required marking before making them available on the GB market.

[*Similar to 'suppliers' as the TRPR defines them.]

This is the declaration that they meet all the requirements of relevant UK legislation, in this case the Electrical Equipment (Safety) Regulations 2016.

The UKCA mark was intended to replace the EU's CE mark after Brexit. However, due to rising costs for businesses, among other things, the Government is currently allowing either mark to be used for most products.

See the '[Electrical equipment](#)' guide for more information on the requirements for manufacturers, importers and distributors.

Trade marks

Trade marks are a form of 'intellectual property' that, when registered with the UK Intellectual Property Office (IPO), can be important and valuable business assets. Your business and brands can be instantly recognised and associated with their registered trade marks. Words, logos and shapes, for example, can be used as trade marks as long as they are unique and not capable of being confused with another trade mark. In addition, they must not:

- be offensive
- be descriptive - for example, the word 'vape' could not be used as a trade mark for vaping products
- mislead
- be generic shapes or commonly used words
- use national flags without permission
- use official hallmarks or emblems

Once registered, a trade mark owner has the right to:

- use the registered trade mark symbol (®)
- license the use of the trade mark by others

A trade mark owner also has the right to take legal action against those who use their trade mark without permission, such as counterfeiters.

Suppliers must ensure that the vaping products they buy for onward sale are provided by legitimate and licensed businesses, and are genuine and authorised products.

Trading Standards services enforce the Trade Marks Act 1994 in relation to the unauthorised use of trade marks on goods.

Further [information on trade marks](#) can be found on the GOV.UK website. See also the '[Intellectual property](#)' guide.

Red flags: are you non-compliant?

Below is a non-exhaustive list that will help you to understand whether you are complying with the law in relation to your position within the supply chain:

- have the vaping products been notified to the MHRA?
- have you completed your annual report to the MHRA?
- are the vape tank size, nicotine-containing liquid and container restricted to the legal maximum?
- are the vaping products and their packaging child resistant and tamper evident?
- is the labelling compliant?
- does the product contain any ingredients other than those that have been notified?
- is the traceability information for the manufacturer and importer present?
- are your non-nicotine vaping products compliant with GPSR?
- have you registered your trade mark?
- are you engaging in the unauthorised use of a trade mark?

Vapes as medicinal products

This guide does not cover the laws that apply to vapes used as medicinal products. For more information, see the MHRA [guidance for licensing vaping products as medicines](#) on the GOV.UK website.

Chemical safety

Information on the requirements of assimilated Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (known as GB CLP) can be found in '[Chemical safety of vapes](#)'.

Note: GB CLP has a different definition of supplier to that contained in the TRPR, so please read the guidance carefully.

MHRA guidance for producers

MHRA has produced [advice for retailers and producers of vapes](#).

Among other things, it includes the following:

- guidance for producers on putting a new product on to the UK market
- how to work out whether, in legal terms, you are a 'retailer' or a 'producer'
- advice for retailers of vapes and nicotine-containing e-liquids
- regulator profiles

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