



OPEN ACCESS

Labelling of electronic cigarettes: regulations and current practice

Federico Buonocore, Ana C N Marques Gomes, Shereen Nabhani-Gebara, Stephen J Barton, Gianpiero Calabrese

Department of Drug Discovery, Delivery and Patient Care, School of Pharmacy and Chemistry, Kingston University, Kingston-upon Thames, London, UK

Correspondence to

Dr Gianpiero Calabrese, Department of Drug Discovery, Delivery and Patient Care, School of Pharmacy and Chemistry, Kingston University, Kingston-upon Thames, London KT1 2EE, UK; G.Calabrese@kingston.ac.uk

Received 14 September 2015

Revised 23 December 2015

Accepted 29 December 2015

ABSTRACT

Background Over the past decade e-cigarettes have established themselves in the global market. E-cigarettes triggered much interest in relation to their content and efficacy as smoking cessation tools, but less attention has been paid to users and environmental safety warnings and guidance. Several regulations have been introduced to promote their safe handling and disposal. From May 2016, liquids and cartridges will be regulated by European Community Directives (ECDs) 2001/83/EC and 93/42/EEC, or 2014/40/EU if marketed as tobacco-related products. Currently, manufacturers and distributors must abide by the Chemical (Hazard Information and Packaging for Supply) Regulations 2009 (CHIP) or Classification, Labelling and Packaging Regulations (CLP), the latter replacing CHIP in June 2015.

Objective In this work, the compliance of marketed e-liquids and e-cigarettes with current European Union and UK legislations is assessed.

Results E-liquids and e-cigarettes (21 and 9 brands, respectively) were evaluated. Evidence of non-compliance was found in relation to the CHIP/CLP toxic (13%) and environmental (37%) pictograms, tactile warning (23%), nominal amount of solution (30%), supplier contact telephone number and address (40%). None of the evaluated e-cigarettes displayed information on the correct disposal/recycling of batteries in line with the ECD 2006/66/EC.

Conclusions More stringent enforcement of regulations is needed to ensure not only the user's safety and awareness, but also the safeguarding of the environment.

The chemical composition of e-cigarettes is not the only concern. E-cigarettes may constitute a potential risk to public health as the effects of their long-term use are still unclear. Their use and sales have drastically increased with an estimated 1.3 million users in the UK alone: a market worth £340 million by 2015.¹ Also, the advertisement of e-cigarettes in the media has been a contributing factor to their commercial growth. In 2013, the Medicines and Healthcare products Regulatory Agency (MHRA) announced e-cigarettes would be fully regulated by 2016.² In 2014, the European Parliament voted for a dual regulation approach: resting entirely on the discretion of the producer, they could be regulated as medicinal products (if marketed as quitting aids) accordingly with Directive 2001/83/EC and 93/42/EEC, or as tobacco-related products subject to the 2014/40/EU Directive with consequent restrictions on advertisements. E-liquids and cartridges will have to comply with European Directives by May 2016. Currently, in the UK e-cigarettes components (not their content) are regulated by the Electrical Equipment (Safety) Regulations of 1994, the Waste Electrical and Electronic Equipment (WEEE) and the Restriction of Substances Hazardous to Health (RoHS) Directives.³⁻⁴ These define the standards for safety, marking and testing of all the electronic components of e-cigarettes (as shown in [table 1](#)) and will remain in force after May 2016.

Also, suppliers of e-liquids and cartridges containing a concentration of nicotine higher than 0.1%⁵⁻⁶ must label packaging according to the Chemical (Hazard Information and Packaging for Supply) Regulations 2009 (CHIP)⁷ or in accordance with Classification, Labelling and Packaging Regulations (CLP),⁸ the latter replacing CHIP in June 2015, which are enforced by Local Authorities in the UK.

CHIP fulfils the European Dangerous Preparations Directive (No. 1999/45/EC) and Dangerous Substances Directive (No. 67/548/EEC). Its most recent issue (CHIP4) became law on 6th of April 2009. The aim of the law is the regulation and control of classification, packaging and labelling of dangerous substances and preparations, and for measures relating to consumer protection, in order to safeguard people and environment from the harmful effects of the chemicals.⁷ This regulation is not applied to all chemicals; for medicines and cosmetics more specific laws are in force. All chemical suppliers have to comply with CHIP4 and under UK legislation suppliers are defined as those who: sell, offer for sale or provide commercial samples, import, or transfer

INTRODUCTION

E-cigarettes are battery-powered devices containing a heating element, which converts a solution into a vapour without burning as in conventional tobacco cigarettes. The liquid solution is generally made of propylene glycol and/or vegetable glycerine, water, nicotine, flavours and colourants. These apply to both e-liquids and cartridges of e-cigarettes. Nowadays, there is a wide range of e-cigarettes (eg, disposable, re-chargeable and tank-style) available for purchases, with variations in nicotine concentrations, aromas and different ratios of glycol/glycerine.

Since their introduction on the market the scientific community has highlighted the lack of quality control in the manufacture of these products and raised concerns regarding the safety of their content.

To cite: Buonocore F, Marques Gomes ACN, Nabhani-Gebara S, et al. *Tob Control* Published Online First: [please include Day Month Year] doi:10.1136/tobaccocontrol-2015-052683

Research paper

Table 1 Summary of requirements that e-cigarettes must comply with

Component	Requirement
Charger	Have to comply with one of these standards BS EN 61558-1: 1998, BS EN 61558-2.6: BS 1363 Part 1 or a more recent one ⁴
Battery	Needs to be labelled with the crossed out wheeled bin symbol
Hardware	Should contain documentation to show compliance with RoHS
Packaging	Must clearly display instruction for the safe use of the device and disposal instructions
E-cigarettes	Must be labelled with the CE logo, clearly displayed on the product, packaging or the instructions. The omission or the incorrect application of the CE logo on any electronic equipment is illegal

RoHS, Restriction of Substances Hazardous to Health.

chemicals from workplace to workplace.⁷ The classification of a chemical consists of defining and explaining the hazards of the chemical using Risk Phrases (R-phrases) and presenting the safety measures to be adopted in case of emergency by using Safety Phrases (S-phrases). In accordance with CHIP4, suppliers must classify chemicals using a harmonised classification (agreed at European level for commonly used chemicals) or using a self-classification (for less common chemicals or mixture of substances). To inform consumers about hazards and safety, CHIP4 specifies the labelling requirements as summarised below:⁷

1. The name, full address and telephone number of a person in an European Economic Area (EEA) State who is responsible for supplying the preparation, whether that person be its manufacturer, importer or distributor;
2. The trade name or other designation of the preparation;
3. Identification of the constituents of the preparation which result in it being classified as a dangerous preparation;
4. Any indication of danger together with corresponding symbols (shape of a square with a black symbol on an orange background with a black frame);
5. The R-phrases and S-phrases, set out in full;
6. In the case of a preparation intended for sale to the general public, the nominal quantity (nominal mass or nominal volume);
7. Tactile warning of danger in accordance with EN-ISO11683 and a child-resistant fastening.

In June 2015, CHIP4 was replaced by CLP to align the EU system of classification, labelling and packaging of chemical substances and mixtures to the Globally Harmonised System (GHS). The latter became law throughout the European Union in January 2009;⁸ however to give manufactures and suppliers time to adapt to the new regulation a 6-year transitional period⁷ was granted. CLP gives detailed information on how to package and label dangerous substances and preparations placed on the market; the requirements are as summarised below:⁸

1. Name, address and telephone number of the supplier(s);
2. The nominal quantity of the substance or mixture in the package where this is being made available to the general public, unless this quantity is specified elsewhere on the package;
3. Product identifiers;
4. Hazard pictograms, where applicable (shape of a square set at a point have a black symbol on a white background with a red frame);
5. The relevant signal word, where applicable;
6. Hazard statements, where applicable;

7. Appropriate precautionary statements, where applicable;
8. A section for supplemental information, where applicable.
9. Tactile warning of danger in accordance with EN ISO 11683 and a child-resistant fastening.

Both regulations outline how to label dangerous substances and methods of marking or labelling packages. These regulations must be respected by suppliers of nicotine-containing products due to the toxicity of nicotine. Nicotine it is well known to be addictive when injected or inhaled and it is the main cause of tobacco dependency.^{9–10} In small amounts nicotine has a stimulant and relaxant effect,^{11–12} however in larger amounts it can be toxic with an estimated lethal dose of 30–60 mg (0.5–1.0 mg/kg of body weight).^{13–15} In recent years, this value has been debated, in particular by Mayer¹⁶ who reported a lethal dose of 6.5–13 mg/kg of body weight. The Electronic Cigarette Industry Trade Association (ECITA) delegated an independent toxicology company (Bibra) to evaluate the dermal and oral toxicity of nicotine, which they report at 50 mg/kg of body weight.¹⁷ Nevertheless, 30–60 mg is still generally used in the safety aspect of tobacco products.^{16–18} Accordingly, there is a requirement for nicotine and its mixtures to be fully labelled under CHIP and CLP regulations.

In this study, the labelling, packaging and clarity of information leaflets for e-liquids and e-cigarettes were investigated and their compliance with regulations in force was assessed.

METHODS

A search was conducted online to identify common e-liquids and e-cigarettes available on the UK market. Search engines used included: Google, Bing, Yahoo! and Ask. Search terms used included: e-cigarettes, electronic cigarettes, electronic nicotine delivery systems, e-liquids. Owing to the complexity and ever changing nature of the market and based on the search results, 21 brands of e-liquids and 9 of e-cigarettes were selected for the study to have a general view and representation of the market. All items were purchased from .co.uk domains. All the sample e-liquids and cartridges were purchased online from UK manufacturers or importers, except for Ezi which was purchased from a high street shop, in February and March 2015. It is noteworthy that many of the products which were purchased online are also widely available for purchase in local shops/pharmacies.

On receipt of the products, all materials were photographed using a Samsung S4 GT9005. Three checklists of required criteria were designed to evaluate the conformity of each product received. Primary and secondary packaging of e-liquid bottles, e-cigarettes and kits were evaluated. The criteria for Checklist A were extracted from CHIP4 and included:

- A. Trade name or other designation of the product.
- B. The identification of all constituents which result in it being classified as hazardous.
- C. Name, full address and contact number of the supplier.
- D. Prevent escape of the chemical.
- E. Child-resistant fastening.
- F. Tactile warning device.
- G. Toxic and environment pictograms.
- H. Risk and safety phrases in full.

The criteria for checklist B were extracted from CLP and included:

- A. The name, address and telephone number of the supplier(s).
- B. Name of the chemical.
- C. Nominal quantity.
- D. Prevent escape of the chemical.
- E. Child-resistant fastening.
- F. Tactile warning device.

G. Toxic and environment pictograms.

H. Hazard statements and precautionary statements.

The criteria for checklist C were extracted from RoHS, Electrical equipment (safety) Regulation of 1994 and WEEE and included:

A. C E mark

B. WEEE

C. Instructions for safe use of product

D. Disposal and recycling of batteries information

E. RoHS

F. Wheelie bin logo on battery

Other aspects such as clarity of instructions and disposal were also evaluated. All reported percentages are rounded up to the next integer.

RESULTS

Twenty-one brands of e-liquids were evaluated. Bottles differed in shapes and volumes; some being aroma therapy bottles which presented a pipette-fitted lid, others being dropper bottles. The conformity of the packaging and labelling to CHIP4 and CLP was evaluated as shown in [tables 2 and 3](#). Nine brands of e-cigarettes were also evaluated and their conformity of the packaging and labelling to CHIP4 and CLP is shown in [tables 4 and 5](#).

Details of suppliers

Of the evaluated e-liquids and e-cigarettes (21 and 9 brands, respectively), an overall of 40% of the products did not clearly display a contact telephone number and address of supplier on the labels. E-liquids tended to be less compliant than e-cigarettes in this respect. It is worth noting that some e-liquids only failed to report a telephone contact number (namely Magnificig, Blue

Table 3 Summary of percent compliance for e-liquids with CHIP4

Brand name	CHIP4									
	A	B	C	D	E	F	G	H	I	J
Magnificig	✓	✓	×	✓	✓	✓	✓	✓	×	✓
Blue Star	✓	✓	×	✓	✓	✓	✓	✓	✓	×
Bestcigliquid	✓	✓	×	✓	✓	✓	✓	✓	×	✓
Totally wicked	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
TECC	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Apollo	✓	✓	×	✓	✓	✓	✓	✓	×	✓
Vapouriz	✓	✓	✓	✓	✓	✓	✓	✓	½	✓
Blu	✓	✓	✓	✓	✓	✓	✓	✓	½	✓
Paradise Vape UK	✓	✓	×	✓	✓	✓	×	×	×	×
Red Vape Ltd	✓	✓	✓	✓	✓	✓	✓	✓	½	✓
Njoy	✓	✓	✓	✓	✓	✓	✓	×	✓	✓
Jac Vapour	✓	✓	×	✓	×	✓	✓	×	✓	✓
Vapourlites	✓	✓	×	✓	✓	✓	✓	✓	½	×
Intellicig	✓	✓	✓	✓	✓	✓	✓	✓	×	✓
OK Electroinic Trading Ltd.	✓	✓	×	✓	✓	✓	✓	✓	×	✓
Innovapours	✓	×	×	×	✓	✓	✓	×	✓	×
Epic Juice LLC	✓	✓	✓	✓	✓	✓	✓	✓	½	✓
Eshisha	✓	✓	×	✓	✓	✓	✓	×	✓	✓
Space Jam	✓	✓	×	✓	✓	✓	✓	×	×	×
Virgin Vapor	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Ezi-cig	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
% Comply	100	95	48	95	95	100	95	71	67	76

Calls identified with the symbol ½ were still counted as ticks.
CHIP4, Chemical (Hazard Information and Packaging for Supply).

star, Apollo, Jac vapour, Vapourlites, @K e-liquid, Eshisha) or just reported a telephone contact number (namely Bestcigliquid and Innovapours).

Table 2 Summary of percent compliance for e-liquids with CLP

Brand name	CLP							
	A	B	C	D	E	F	G	H
Magnificig	×	✓	✓	✓	✓	✓	×	✓
Blue Star	×	✓	✓	✓	✓	✓	✓	×
Bestcigliquid	×	✓	✓	✓	✓	✓	×	✓
Totally wicked	✓	✓	✓	✓	✓	✓	✓	✓
TECC	✓	✓	✓	✓	✓	✓	✓	✓
Apollo	×	✓	✓	✓	✓	✓	×	✓
Vapouriz	✓	✓	✓	✓	✓	✓	½	✓
Blu	✓	✓	✓	✓	✓	✓	½	✓
Paradise Vape UK	×	✓	✓	✓	×	×	×	×
Red Vape Ltd	✓	✓	✓	✓	✓	✓	½	✓
Njoy	✓	✓	✓	✓	✓	×	✓	✓
Jac Vapour	×	✓	×	✓	✓	×	✓	✓
Vapourlites	×	✓	✓	✓	✓	✓	½	×
Intellicig	✓	✓	✓	✓	✓	✓	×	✓
OK Electroinic Trading Ltd	×	✓	✓	✓	✓	✓	×	✓
Innovapours	×	×	✓	✓	✓	×	✓	×
Epic Juice LLC	✓	✓	✓	✓	✓	✓	½	✓
Eshisha	×	✓	✓	✓	✓	×	✓	✓
Space Jam	×	✓	✓	✓	✓	×	×	×
Virgin Vapor	✓	✓	✓	✓	✓	✓	✓	✓
Ezi-cig	✓	✓	✓	✓	✓	✓	✓	✓
% Comply	48	95	95	100	95	71	67	76

Calls identified with the symbol ½ were still counted as ticks.
CLP, Classification, Labelling and Packaging.

Table 4 Summary of percent compliance for e-cigarettes with CLP

Type	Brand name	CLP							
		A	B	C	D	E	F	G	H
Rechargeable	TABLites	✓	✓	×	✓	✓	✓	½	✓
Rechargeable	E-Lites	✓	✓	×	✓	✓	✓	½	✓
Rechargeable	VIP	✓	✓	×	✓	✓	✓	½	✓
Rechargeable	Freshcig	✓	✓	×	✓	✓	✓	✓	✓
Disposable	Vapourlites	✓	✓	×	✓	✓	×	½	✓
Disposable	Intellicig	✓	✓	×	✓	✓	✓	×	✓
Disposable	Nicolites	✓	✓	✓	✓	✓	✓	×	✓
Disposable	OK Electronic Trading Ltd.	×	✓	×	✓	✓	✓	×	✓
Disposable	Ezi-cig	✓	✓	×	✓	✓	✓	½	✓
	% Comply	89	100	11	100	100	89	67	100

Calls identified with the symbol ½ were still counted as ticks.
A. The name, address and telephone number of the supplier(s).
B. Name of the chemical.
C. Nominal quantity.
D. Prevent escape of the chemical.
E. Child-resistant fastening.
F. Tactile warning device.
G. Toxic and environment pictograms.
H. Hazard statements and precautionary statements
½ Toxic pictogram only.
* Harmful pictogram.
CLP, Classification, Labelling and Packaging.

Research paper

Table 5 Summary of percent compliance for e-cigarettes with CHIP4

Type	Brand name	CHIP4									
		A	B	C	D	E	F	G	H	I	J
Rechargeable	TABlites	✓	✓	✓	✓	×	✓	✓	✓	½	✓
Rechargeable	E-Lites	✓	✓	✓	✓	×	✓	✓	✓	½	✓
Rechargeable	VIP	✓	✓	✓	✓	×	✓	✓	✓	½	✓
Rechargeable	Freshcig	✓	✓	✓	✓	×	✓	✓	✓	✓	✓
Disposable	Vapourlites	✓	✓	✓	✓	×	✓	✓	×	½	✓
Disposable	Intellicig	✓	✓	✓	✓	×	✓	✓	✓	×	✓
Disposable	Nicolites	✓	✓	✓	✓	✓	✓	✓	✓	×	✓
Disposable	OK Electronic Trading Ltd.	✓	✓	×	✓	×	✓	✓	✓	×	✓
Disposable	Ezi-cig	✓	✓	✓	✓	×	✓	✓	✓	½	✓
	% Comply	100	100	89	100	11	100	100	89	67	100

Calls identified with the symbol ½ were still counted as ticks.

A. Trade name or other designation of the product.

B. The identification of all constituents which result in it being classified as hazardous.

C. Name, full address and contact number of the supplier.

D. Name of the chemical.

E. Nominal quantity.

F. Prevent escape of the chemical.

G. Child-resistant fastening.

H. Tactile warning device.

I. Toxic and environment pictograms.

J. Risk and Safety phrases in full.

½Toxic pictogram only.

*Harmful pictogram.

CHIP4, Chemical (Hazard Information and Packaging for Supply).

Nicotine and nominal quantity

E-liquids and e-cigarettes contained varying amounts of nicotine. Manufacturers adopt different labelling systems to inform consumers about the amount of nicotine present in their products. Usually the amount of nicotine is reported in mg; however it is not clear whether this refers to the entire liquid, or represents the amount of nicotine per millilitre of solution. Other methods consist of reporting the concentration of nicotine as percentage or as mg/mL. In all cases, the total amount of nicotine was never reported, which has also been previously reported in the literature.^{19 20} Among all samples, it was noticed that Magnificig reports two different values for nicotine content on the secondary packaging (figure 1) and a single volume on the label of the bottle. This is contradictory and can lead to confusion for consumers.

Other manufactures such as Blue Star reported the nicotine amount on small stickers which may be easily peeled off or lost during transportation. Of the total e-liquids and e-cigarettes,

76.5% did not state that nicotine is an addictive drug. Also, it was observed that some brands present written warnings for consumers of nicotine-containing products with underlying conditions such as high-blood pressure or cardiovascular diseases.^{14 21–23} However, 70% of the investigated products failed to do so. Also, it was found that 53% of samples did not report any warning for pregnant women or breast feeding mothers. Despite not being compulsory for manufacturers and some professional organisations advocating electronic cigarettes as a safer option for pregnant women,²⁴ warning phrases should appear on both packaging and labels as nicotine represents a threat to unborn babies and it may be harmful for the fetus.^{25 26}

Products, both chemicals and preparations, which are meant to be sold to the general public, must be labelled with the nominal amount, which is the amount of chemical or solution present in the container, for example, bottle. This value can be reported in weight or volume. In this study, it was found that 30% of the products (e-liquids and e-cigarettes combined) did

Figure 1 Contradictory information reported on secondary packaging of Magnificig is highlighted by yellow ellipses.



not report the amount of solution, with a high contribution from e-cigarettes only. Disposable Nicolites cigarettes were the only product reporting the volume of solution, which in addition with the reported concentration in mg/ml would fully inform the consumer of the amount of nicotine.

Child-resistant closure

Child-resistant closures consist of a specially designed closure used to reduce the risk of children coming into contact with dangerous substances. These safety closures are applied to dangerous chemicals, intended for sale to the general public. All the evaluated samples were fitted with a child-resistant fastening with the exception of one, which was labelled as 'Low' in nicotine.

Tactile warnings

A tactile warning device consists of an altered surface generally made of a raised triangular shape or three dots. Tactile warnings alert visually impaired consumers, who use under-fingers detection, when handling a toxic, very toxic, corrosive, harmfully or extremely flammable substance. In this study, 23% of the samples did not display any tactile warning, while the rest had a triangular shape that was present as sticker or moulded on the lid of the e-liquids.

Pictograms

According to different authorities' guideline classifications,^{5 6} mixtures containing nicotine with a percentage higher than 1% should be labelled with a toxic pictogram. In this study, it was found that 33% of brands did not show this on the label. Other brands (20%) reported pictograms which do not conform to CHIP and CLP.

List of the ingredients

The list of ingredients is an important source of information for the consumer about the content of the product. For food and medicines, ingredients are listed in order of decreasing amounts; hence the first labelled ingredient is the most abundant. In this study, it was found that 13% of products did not report any list of ingredients, with one brand (ie, Apollo) reporting 'may contain' for its ingredients. Also, Blue Star bore the wordings 'approved flavours' and 'approved colourings'. Others stated food grade flavouring or own made flavouring agents. In 40% of cases, manufactures reported flavours before nicotine, which may suggest these were present in higher amounts as compared to nicotine.

Traceability

Traceability plays a pivotal role in the safety of the products, allowing manufactures to identify the source of all the raw materials, ingredients and packaging. This information enables the

producer or the trader to track a product if a safety problem or concern arises, and to withdraw the product from the market reducing potential public health risks. Of the investigated brands, 13% did not present any form of traceability such as barcode or batch number.

R-phrases and S-phrases/hazard and precautionary statements

R-phrases and S-phrases (according to CHIP4) and H (Hazard) and P (precautionary) statements (as outlined by CLP) are an array of phrases which highlight the health risk and the safety advice attributed to dangerous substances or their preparations. These phrases are defined by different European Union Directives 2001/59/EC, 2006/102/ and 1272/2008/EC and are recognised and used worldwide. In this study, the presence of the following R-phrases and S-phrases and H and P statements was evaluated: 'very/toxic if swallowed', 'toxic in contact with the skin', 'lethal in contact with the skin', 'May cause long-term adverse effects in the aquatic environment', 'After contact with skin, wash immediately with plenty of water and soap', 'If swallowed, seek medical advice immediately and show this container or label'. It was found that 16.5% of the samples did not report any of the above R-phrases and S-phrases.

Conformity of e-cigarettes

The nine brands of e-cigarettes were also evaluated and their conformity of labelling to Electrical Equipment (Safety) Regulations of 1994, WEEE and RoHS was evaluated as shown in [table 6](#).

DISCUSSION

The results of this study show that apart from few instances, the majority of e-liquids and e-cigarettes manufacturers/distributors do not fully comply with currently enforced regulations, namely CHIP4 or CLP, Electrical Equipment (Safety) Regulations of 1994, WEEE and RoHS.

The lack of (or presence of misleading) information on the label of these products has potential implications in terms of safety that are considerable. Total amount of nicotine present in the e-liquids and e-cigarettes should be clearly reported on the label so as to inform the consumers through the combination of concentration information and nominal quantity, and avoid consumers to intake more nicotine than desired, potentially increasing their dependency. As nicotine is the chemical component of these products directly connected to potential hazards, it is paramount to have a clear indication of the nicotine content on labels. Contradictory information has emerged in regard to the threshold level of nicotine, below which self-classification is allowed. More consistent measures are required in this respect as this is directly related to safety issues. In recent years, there has been an increase of calls to the United States and UK poison

Table 6 Summary of e-cigarettes compliance with Electrical Equipment (Safety) Regulations of 1994, WEEE and RoHS

Requirements	Vapourlites	TABLites	E-Lites	Intelligig	Nicolites	OK	Ezi-cig	VIP	Fresh	Percentage of Comply
C E mark	✓	✓	✓	✓	✓	✓	✓	✓	✓	100
WEEE	✓	✓	✓	✓	✓	✓	✓	✓	✓	100
Instructions for safe use of product	×	✓	✓	✓	✓	✓	×	✓	✓	78
Disposal and recycling of batteries information	×	×	×	×	×	×	×	×	×	0
RoHS	✓	✓	✓	✓	✓	×	×	✓	✓	78
Wheellie bin logo on battery	✓	✓	✓	×	×	×	✓	✓	×	56

RoHS, Restriction of Substances Hazardous to Health; WEEE, waste electrical and electronic equipment.

Research paper

centres for children who had come in contact with solutions containing nicotine for e-cigarettes use.^{27 28} The main physical consequences were vomiting, nausea and eye irritation. Also, a lethal case²⁹ was recorded in the past 2 years. A child-resistant fastening of e-liquid bottle was not found on one of the evaluated samples (ie, a free sample of Bubbalicious flavour from Paradise Vape UK); this poses serious concerns regarding the reliability of production in terms of respect of current regulations.

Clarity of information regarding the content is not only restricted to nicotine. Labels play a pivotal role in cases of emergencies, when clinicians would refer to them to evaluate the level of exposure that victims have been in contact with. A full list of ingredients and the potential implications for consumers with underlying conditions should be provided in the information leaflets. For instance, Blue Star e-liquid bore the wordings 'approved flavours' and 'approved colourings', for which the authors were unable to ascertain the nature and amounts. This could constitute a risk in case of specific allergies consumers may present.

In order to minimise risks of exposure of unaware members of the public to these products tactile warnings and relevant pictograms must be present on all types of packaging. Tactile warnings were not found in 29% of e-liquids and in only 1 e-cigarette. This would place visually impaired consumers in a clearly disadvantaged or vulnerable position. Also, many evaluated products were not found to fully meet the requirements regarding the presence of pictograms. A total of seven e-liquids and three e-cigarettes displayed no toxic or environmental pictograms on labels; these include those instances where a harmful pictogram was reported instead. Other brands (20% of the total) reported pictograms which were made to look friendlier by changing the colours or the shape of the backgrounds and therefore making them less eye-catching. All these instances are to be classified as non-compliance under CHIP and CLP, as the specifications for pictograms are clear in terms of shape, colours and sizes. Some brands (5 e-liquids and 5 e-cigarettes) did not report the environmental pictogram while displaying the toxic one, raising concerns regarding the potential impact these products may have on the environment in the long run.

Information regarding correct disposal must be displayed clearly as nicotine can produce carcinogens³⁰ and leak into groundwater which may affect the aquatic life. For this reason environmental protection action should be considered by authorities when designing legislations. The WEEE Directive 2002/96/EC has defined the crossed-out wheeled bin symbol, also known as the wheelie bin logo. In addition to the CE symbol, this logo shows that the electrical equipment must not be disposed of in the general waste stream, with the aim to reduce the hazardous substances in the environment. All e-cigarettes considered in this work claim on their label to agree with WEEE and as a result the wheelie bin logo appeared in all products. However, in 44% of the samples this logo was not present on the battery itself as prescribed by article 21 of the same directive.³¹ Additionally, it also emerged that none of the evaluated e-cigarettes report any information regarding the disposal and recycling of batteries sold as part of the product.

E-liquids and e-cigarettes labelling do not fully comply with the enforced regulations apart from few exceptions. Local authorities are responsible for the enforcement of the regulations and, in case of non-compliance, prosecution and fines should be applied.⁴ However, local authorities may only be able to enforce regulations on territories under their jurisdiction, but not on the online market on a national scale. The evidenced non-compliance results in a generally poor quality of labels

which may expose members of the public to health risks and constitute a potential threat to the environment. If quality of labels does not improve, consumers will not be aware of the risk associated with these products and their contents, which may potentially result in accidents and/or unwanted exposure to a toxic substance, especially for vulnerable people such as children and visually impaired individuals. More stringent regulations or a better enforcement of the currently existing ones are desirable in the near future to ensure not only the safety and full information of consumers, but also the respect of the environment.

What this paper adds

- ▶ E-cigarettes have attracted much interest in relation to their content and efficacy as smoking cessation tools. Less attention has been paid to safety warnings and guidance to users and for the environment. Regulations currently exist to promote their safe handling and disposal.
- ▶ This work investigates the compliance of the labelling, packaging and clarity of information leaflets of e-liquids and e-cigarettes with regulations currently in force.
- ▶ The majority of e-liquids and e-cigarettes manufacturers/distributors do not fully comply with currently enforced regulations. The safety implications are considerable; especially for specific users groups. Improvements in the current practice and a better enforcement of the currently existing regulations are necessary.

Acknowledgements This work was funded by Kingston University London. The authors thank Hamzeh Khademi, Akua Amponsah and Mehreen Munir, for their contribution to the study.

Contributors FB has performed the audit and drafted the article. ACNMG has contributed to the article offering expertise in regulatory affairs. SN-G and SJB have co-designed the study and contributed to the article (content). GC has co-designed the work, analysed the data, contributed to the article and submitted work.

Competing interests None declared.

Provenance and peer review Not commissioned; externally peer reviewed.

Open Access This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>

REFERENCES

- 1 Bauld L, Angus K, de Andrade M. E-cigarette uptake and marketing A report commissioned by Public Health England. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311491/Ecigarette_uptake_and_marketing.pdf (accessed 7 Mar 2015).
- 2 Medicines and Healthcare products Regulatory Agency (MHRA). Licensing Procedure for Electronic Cigarettes and Other Nicotine Containing Products (NCPs) as Medicines. <http://www.mhra.gov.uk/home/groups/comms-ic/documents/websitesources/con297583.pdf> (accessed 11 Mar 2015).
- 3 Trading Standards—Derbyshire County Council. Selling Electronic Cigarettes (E-cigs). http://www.derbyshire.gov.uk/images/sfy31_tcm44-247854.pdf (accessed 12 Mar 2015).
- 4 Sheffield Trading Standards. Product Safety Information Sheet e-cigarettes & liquids. https://www.sheffield.gov.uk/dms/scc/management/corporate-communications/documents/business-industry/trading-standards/Electronic_Cigarettes_Guidance.pdf (accessed 12 Mar 2015).
- 5 Southwark Council. E-cigarettes and e-shisha product safety. http://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=10&cad=rja&uact=8&ved=0CFQQFjAJ&url=http%3A%2F%2Fwww.southwark.gov.uk%2Fdownload%2Fdownloads%2Fid%2F9085%2Fe-cigarettes_and_e-shisha&ei=tj-VmSKoLvaq

- TRgPAN&usg=AFQjCNEG4-RnbxASZUH2zCcPJ0F_WiwvhQ&bvm=bv.87611401,d.d2s (accessed 10 Mar 2015).
- 6 Hampshire County Council. Electronic cigarettes and e-liquids. <http://www3.hants.gov.uk/tradingstandards/tradingstandards-business/ts-business-safety/tsguide-electronic-cigarettes.htm> (accessed 18 Mar 2015).
 - 7 The Stationery Office Regulations 2009 No. 716 Chemicals (Hazard Information and Packaging for Supply). SI 2009/716 2009 ISBN 978 0 11 147674 1.
 - 8 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
 - 9 Ruffle JK. Molecular neurobiology of addiction: what's all the (Δ)FosB about? *Am J Drug Alcohol Abuse* 2014;40:428–37.
 - 10 Marttila K, Raattamaa H, Ahtee L. Effects of chronic nicotine administration and its withdrawal on striatal FosB/DeltaFosB and c-Fos expression in rats and mice. *Neuropharmacology* 2006;51:44–51.
 - 11 Balfour DJ, Fagerström KO. Pharmacology of nicotine and its therapeutic use in smoking cessation and neurodegenerative disorders. *Pharmacol Ther* 1996;72:51–81.
 - 12 Bass F, McCormack JP. Effective clinical tobacco intervention. *Thorax* 1997;21:1–4. <http://www.ti.ubc.ca>
 - 13 Okamoto M, Kita T, Okuda H, et al. Effects of aging on acute toxicity of nicotine in rats. *Pharmacol Toxicol* 1994;75:1–6.
 - 14 IPCS INCHEM. Nicotine. [http://www.inchem.org/documents/pims/chemical/nicotine.htm#SubSectionTitle:7.2.1 Human data](http://www.inchem.org/documents/pims/chemical/nicotine.htm#SubSectionTitle:7.2.1%20Human%20data) (accessed 20 Mar 2015).
 - 15 Gosselin RE, Smith RP, Hodge HC, et al. *Clinical toxicology of commercial products*, 6th edn. Baltimore, MD: Williams & Wilkins, 1988.
 - 16 Mayer B. How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century. *Arch Toxicol* 2014;88:5–7.
 - 17 Bibratoxicology advice & consulting. EU Classification of nicotine mixtures under CLP Regulation 1272/2008 (as amended and corrected). http://ecita.org.uk/sites/default/files/u41/bibra%20EU_Classification_of_nicotine_mixtures_acute_oral_and_dermal_toxicity.pdf (accessed 25 Mar 2015).
 - 18 Bureau REACH. CLH report Proposal for Harmonised Classification and Labelling. <http://echa.europa.eu/documents/10162/56df129c-42d3-4533-a828-e5d26a58bc63> (accessed 20 Apr 2015).
 - 19 Cameron JM, Howell DN, White JR, et al. Variable and potentially fatal amounts of nicotine in e-cigarette nicotine solutions. *Tob Control* 2014;23:77–78.
 - 20 Goniewicz ML, Kuma T, Gawron M, et al. Nicotine levels in electronic cigarettes. *Nicotine Tob Res* 2013;15:158–66.
 - 21 Sabha M, Tanus-Santos JE, Toledo JC, et al. Transdermal nicotine mimics the smoking-induced endothelial dysfunction. *Clin Pharmacol Ther* 2000;68:167–74.
 - 22 Zhang S, Day I, Ye S. Nicotine induced changes in gene expression by human coronary artery endothelial cells. *Atherosclerosis* 2001;154:277–83.
 - 23 Hawkins BT, Brown RC, Davis TP. Smoking and ischemic stroke: a role for nicotine? *Trends Pharmacol Sci* 2002;23:78–82.
 - 24 Andy McEwen, NCSCT (Public Health England). Smoking Cessation: a briefing for midwifery staff. 2015. http://www.ncsct.co.uk/usr/pub/NCSCCT_midwifery_briefing.pdf (accessed 30 Jul 2015).
 - 25 Behnke M, Smith VC. Prenatal substance abuse: short- and long-term effects on the exposed fetus. *Pediatrics* 2013;131:e1009–24.
 - 26 Bruin JE, Gerstein HC, Holloway AC. Long-term consequences of fetal and neonatal nicotine exposure: a critical review. *Toxicol Sci* 2010;116:364–74.
 - 27 Chatham-Stephens K, Law R, Taylor E, et al., Centers for Disease Control and Prevention. Notes from the field: calls to poison centers for exposures to electronic cigarettes—United States, Sept 2010–Feb 2014. *MMWR Morb Mortal Wkly Rep* 2014;63:292–3. <http://www.cdc.gov/mmwr/pdf/wk/mm6313.pdf> (accessed 26 Mar 2015).
 - 28 NPIS National Poisons Information Service (2014) Report 2013/14, <http://www.npis.org/annualreports.html>: Public Health England.
 - 29 Associated Press. The New York Times Company. Cops: Boy's Death From Drinking Liquid Nicotine Was Accident. http://www.nytimes.com/aponline/2015/04/13/us/ap-us-toddler-nicotine-death.html?_r=0 (accessed 19 Apr 2015).
 - 30 Sleimana M, Gundela LA, Pankowb JF, et al. Formation of carcinogens indoors by surface-mediated reactions of nicotine with nitrous acid, leading to potential thirdhand smoke hazards. *P Natl Acad Sci USA* 2010;107:6576–81.
 - 31 Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC 26.9.2006L 266/12.



Labelling of electronic cigarettes: regulations and current practice

Federico Buonocore, Ana C N Marques Gomes, Shereen Nabhani-Gebara, Stephen J Barton and Gianpiero Calabrese

Tob Control published online January 20, 2016

Updated information and services can be found at:
<http://tobaccocontrol.bmj.com/content/early/2016/01/20/tobaccocontrol-2015-052683>

These include:

References

This article cites 15 articles, 3 of which you can access for free at:
<http://tobaccocontrol.bmj.com/content/early/2016/01/20/tobaccocontrol-2015-052683#BIBL>

Open Access

This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>

Email alerting service

Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

Topic Collections

Articles on similar topics can be found in the following collections

[Open access](#) (267)

Notes

To request permissions go to:
<http://group.bmj.com/group/rights-licensing/permissions>

To order reprints go to:
<http://journals.bmj.com/cgi/reprintform>

To subscribe to BMJ go to:
<http://group.bmj.com/subscribe/>