

The Tobacco and Related Products Regulations 2016 came into full effect in May 2017; this report provides an overview of the compliance of nicotine inhaling devices available online with these Regulations

Rapid Review of Nicotine Inhaling Product Compliance with the Tobacco Product and Related Products Regulations : 2017



Chartered Trading
Standards Institute

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1. Introduction

Kent County Council Trading Standards were commissioned by the Chartered Trading Standards Institute (CTSI) on behalf of the Department of Health (DH) to undertake an online review of products for compliance with the requirements of the Tobacco and Related Product Regulations 2016 (TRP).

This review was in parallel to a national review carried out by three of the Trading Standards regions, in physical retail premises to establish any significant trends in terms of compliance levels. While the national review focussed on up to 300 premises with up to 10 products in each, meaning a total sample of up to 3000 products being examined, this review would look at a sample of up to 30 products.

2. Background to Project

The Tobacco and Related Product Regulations 2016 came into force on 20th May 2016 with a further one-year transition period. E-cigarettes and liquids containing nicotine are required to conform with certain product specifications, labelling requirements (found in Part 6 of the Regulations)¹ and be notified to the Medicine and Healthcare products Regulatory Agency (MHRA)². As over 6 months had elapsed from the end of the transition period, this review seeks to examine compliance levels.

The online sample represented 0.1% of the total number of products in the main review, therefore it would not be possible to give a statistically relevant conclusion of compliance in the online vs offline arena, however it is intended as an indication of the availability of non-compliant product and to highlight potential areas of concern which may require further investigation.

3. Method

In planning the project, a number of online sources were considered, including auction sites, large internet retail sites (particularly those allowing third party sellers), social media sites and any other online retailer such as 'vape clubs'. Due to the existence of the offline review, it was not anticipated to simply visit the online equivalent of a physical High Street store, nor was it the intention to buy products which appeared to be readily available offline.

Products were purposefully selected on the appearance of being non-compliant or because of an inability to check through website images. Non-compliance figures should therefore not be read as an indication of the total online marketplace.

The products were ordered using a Paypal account in the name of an officer, delivered to an office street address (not immediately obvious as a local authority building). Upon delivery of

¹ Part 6 Tobacco and Related Product Regulations 2016
<http://www.legislation.gov.uk/ukxi/2016/507/part/6/made> accessed 23rd March 2018

² Gov.uk website listing currently notified products <https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products> accessed 23rd March 2018

the products, photographs were taken, and an assessment of the product made in line the requirements of the main review i.e.

E cigarettes & refill containers: See Part 6 of the TRPs
Reg 36 product compliant with size requirement
Reg 36 product compliant with nicotine strength requirement
Reg 36 product child resistant & tamper evident
Reg 37 product has information leaflet
Reg 37 product carried health warning
Notification of sample of products : yes / no for each product identified

When searching for products online it was soon found that e-liquids on large internet retail websites were all 0mg and therefore a decision was made early on to focus searches on such sites purely to the e-cigarette devices which could be used to inhale nicotine. Searches for such devices would not always present a device which either way could be concluded to be compliant or not, for instance capacity was rarely given in the product description but was often alluded to in reviews and it was clear that users searching for a known product, knew what they would be looking for. It was also apparent in some cases that EU TPD compliant versions were available alongside non-compliant versions. As an example, a particular model may be re-designed and sold with a 2ml tank in EU countries, but be available with a 4ml tank elsewhere, however the 4ml versions can and do find their way into the UK market. From a customer point of view, a large internet retailer utilising marketplace sellers may find the same product listed differently depending on which marketplace seller they buy from.

Intelligence on Facebook was limited and therefore did not form part of the test purchase phase, especially as it would have added complications to the test purchasing with the potential for Directed Surveillance implications to have to be taken into consideration.

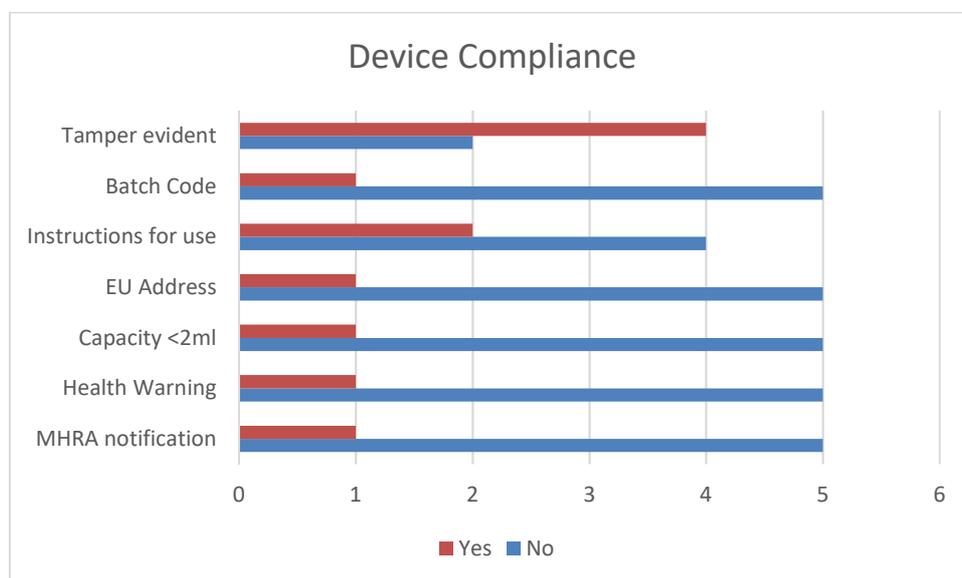
Intelligence on auction websites was however prolific and therefore a number of purchases did focus on such platforms. Anecdotal evidence was also in existence regarding liquids of Malaysian origin therefore a small number of products were specifically sought out to check compliance and these will be commented on below.

4. Results

4.1 Devices

A total of seven devices were purchased, although one on delivery was found to be the 'Mod Box' element, without any nicotine containing parts and would therefore fall outside of MHRA guidance³ for parts requiring notifications/labelling.

Of the six remaining devices, four were purchased through a large internet retailer from third party sellers, although of these three were fulfilled by the actual internet retailer. One product was bought through an auction website and one product was bought from a UK based website which was identified when searching for a model of device rather than searching for that website.



The chart above shows the findings for the six products examined. Of note, one product was a notified product but comes with the caveat that it is a 'Squonk' box subject to current interest and assessment. This one device carried an EU address in the instructions⁴ and the health warning was applied to the box, however the notification to MHRA was non-compliant as the capacity of the 'Squonk bottle' was 8ml yet declared in the notification as 2ml.

³ MHRA e-cigarette product requirements

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/544092/2_Product_type_disc_paper_final.pdf accessed 23rd March 2018

⁴ Tobacco and Related Product Regulations 2016 Regulation 37(2)(f) and (g) require contact details for the producer or EU responsible person on an information leaflet to be supplied with the product, however General Product Safety Regulations 2005 Regulation 7 (4)(a)(i) would require that same information to be present where practical on the packaging

In the majority of cases, no responsible person was given in the EU, with the majority of addresses only given of Chinese manufacturers. In the case of the auction purchase and two of the other devices, no manufacturer details were found at all (example packaging below).



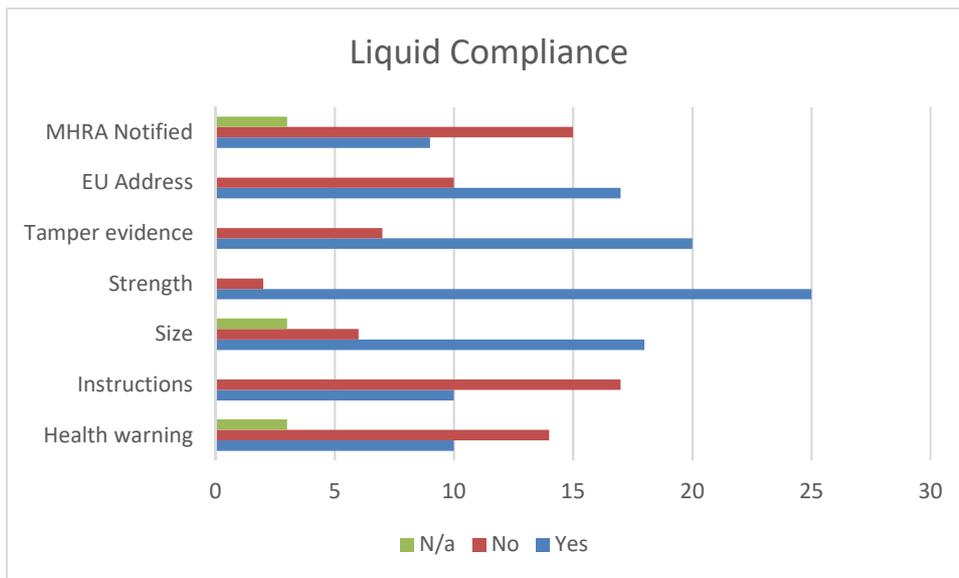
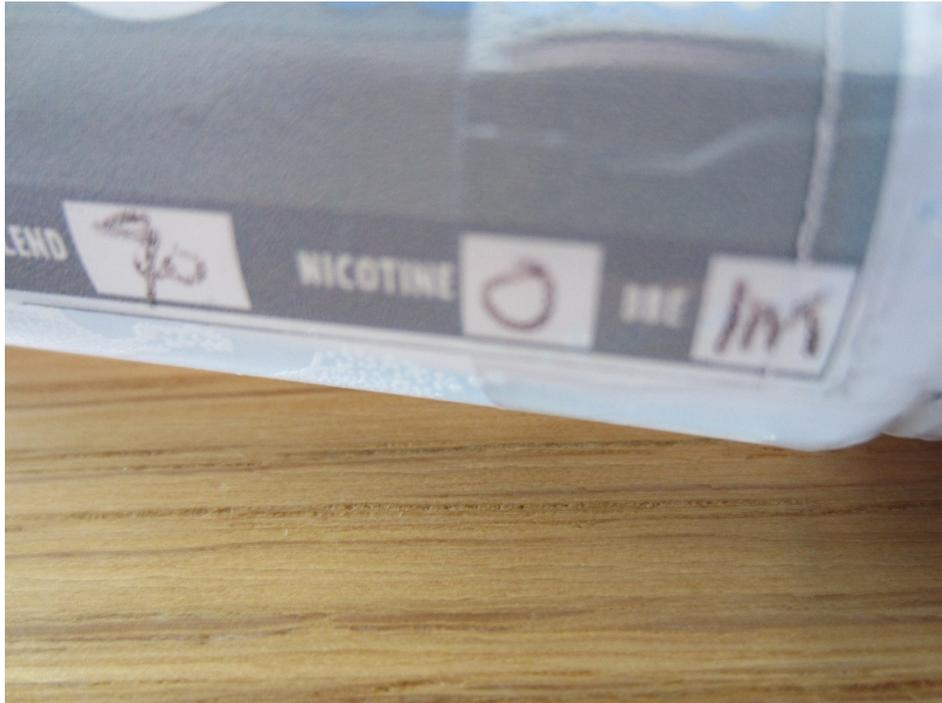
Only one product was test purchased with a tank capacity under 2ml, however this was to be expected as an emphasis was put on purchasing products that were likely to be non-compliant or have TPD compliant/non-compliant variants. What the purchases did show however, was that of the four products bought through the internet retailer, three were fulfilled by them directly meaning they had direct access to the products which were plain to see were non-compliant in the case of two of the three.

4.2 Liquids

In total, 24 e-liquids were ordered, where there was suspicion of non-compliance or compliance could not be ascertained from the website images or information.

Upon delivery three of the products were sent as 0mg liquids accompanied by a 'Nic Shot'. 'Nic shots' are typically TPD compliant bottles of nicotine, supplied in a carrier solution at 18mg/ml. The shot is added to the larger 0mg containing bottle to make a mixed solution of 3mg/ml or 6mg/ml. As a result of receiving three liquids with 'Nic shots', the shots have themselves been assessed for compliance with TPR.

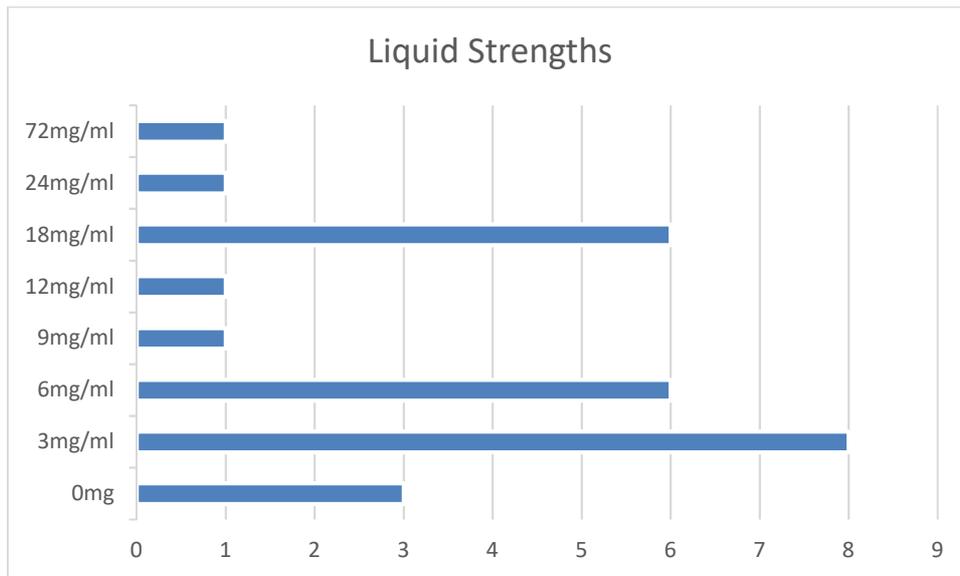
One liquid was advertised as 6mg/ml however was delivered in a 30ml container with a handwritten declaration of 0mg/ml. This product is due to be tested, however is considered to be nicotine containing for the purposes of this report as the reliability of this declaration is considered unlikely.



In the chart above 0mg liquids were referred to as n/a for MHRA notifications, size of refill container and the health warning. However as best practice under the General Product Safety Regulations 2005 [GPSR] they were included within the results for instructions for use and having an EU address.

4.3 Strength of Liquids

As an emphasis was put on finding liquids likely to be non-compliant, part of that criteria was to look for liquids of a strength over 20mg/ml. The chart below shows the strengths of liquid found over the 27 products. Again, three of the products were unregulated 0mg products. Of the remainder, only one was an 'over-strength' 24mg/ml product and one product was a 72mg/ml product intended for mixing with 0mg/ml.



The sale of 72mg/ml liquids is one for current consideration in terms of guidance, however it has to be noted in the context of this purchase, the product was bought from an auction website (a predominantly consumer platform) and made no claims to be for 'trade use only'.

Of the 27 products, 20 can be considered intended for use in the 3-6mg/ml range, taken by virtue of actual strength or being a 0mg product designed to be used with one of the 18mg/ml 'Nic shots'. This finding replicates that seen in the high street setting in that users are showing a preference towards these lower strength liquids, with the 'throat hit' coming from device specification rather than the nicotine itself.

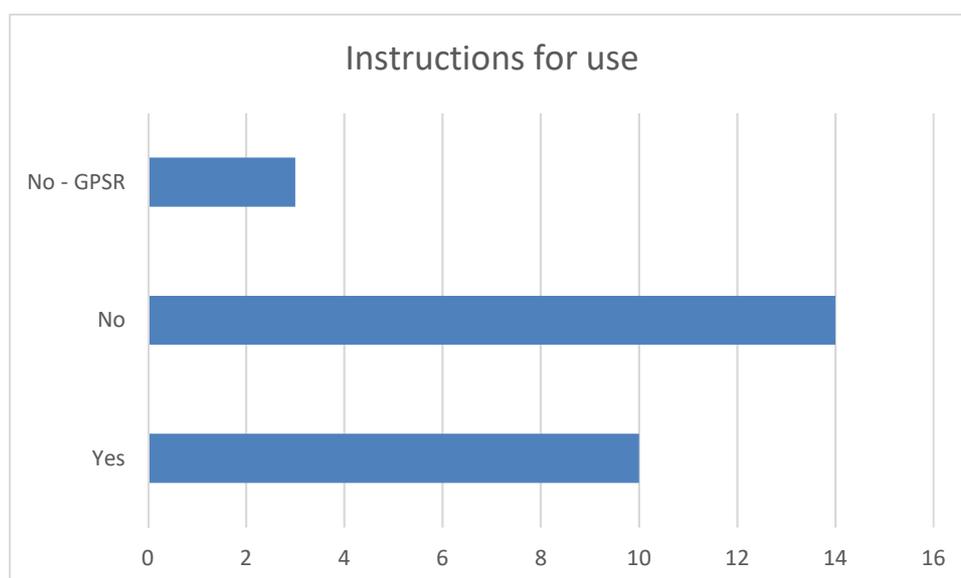
4.4 Health warnings

The health warning was as required on 13 out of 27 products (10 compliant plus three not required). Three of the products found to be non-compliant for health warnings, as well as instructions for use **appeared** to have been split from multi-packs by the distributor (in each case an auction site seller). The basis for this assumption comes from the fact the products are otherwise notified to MHRA and having performed internet searches on the product while verifying the approval status, links were found to the retail packs typically sold as 3 x 10ml.

Prior guidance from MHRA allows for cardboard sleeves to carry the required information **instead** of the individual refill container, which appears to have been the case in this situation. The distributor will of course be liable for making material change to the product information upon supply by breaking the product down from the multipack.

4.5 Instructions for use

Instructions for use were present on ten of the products, matching those compliant for health warnings. The additional three products which didn't require health warning, did not have instructions for use, not required by TPR but would by reasonable conclusion be required under GPSR.



5. MHRA Notifications

Products were all assessed for compliance with the MHRA notification procedure. Three products did not require notification as they were 0mg products. Seven of the products were identified, with a further two latterly found following identification by the manufacturer, however 15 of the products were not notified. The 15 un-notified products can be further broken down into eight TPR 'eligible' products, those which are 10ml and under 20mg/ml (whether or not they have other labelling errors) and seven ineligible products (those over 10ml or over 20mg/ml).

Where products are otherwise eligible, enquiries are currently underway by the MHRA. In the case of products that could not be compliant with TPD (e.g. over 10ml refill bottles), referrals are being made to the local Trading Standards service to the manufacturer where identified or distributor in all other cases.

6. Other Points of Note

- **Batch numbers** for both liquids and devices appeared variable. In one case, the same batch number was seen across a variety of products which had unwittingly been bought from the same manufacturer.
- **Age verification** - Most sellers appear to copy the same phrase on their listings, either in an effort to satisfy a casual inspection of the site, or for the purposes of website policy.

“...have an effective age verification process that satisfies due diligence as described in the Business Companion guide for online age verification checks and will not sell to persons that are under 18 years old”

Having carried out the test purchases, I would disagree that **any** of the sellers complied with the requirements given in the Business Companion guide, although that is not a subject of this report.

- **Malaysian Liquids** - As outlined in the method, some anecdotal information had been provided in respect of Malaysian liquids. It is understood that liquids produced in Malaysia have been formulated in such a way that gives the user a ‘cold’ throat hit when inhaling which hasn’t been easily replicated in other liquids, making these liquids popular with users.

Five products were test purchased with perceived Malaysian links. Three were UK based sellers, of which one product appeared to be broken down from a multi-pack (and leaked), one provided an EU address of a known London based fulfilment house and one appeared otherwise compliant. Two products were purchased from a website selling into the UK from Malaysia. These two tests were to see the ease in which non-compliant product could be purchased from abroad and confirmed the website in question which was not registered to sell to the UK would in fact do so.

The package from Malaysia arrived within days of the order, therefore for a UK user preferring the larger bottle sizes (in this case 50ml) this was clearly an easy option. Customs declarations on the packaging referred to the contents as ‘scented oils’ which is a matter for ongoing discussions with the Ports & Borders team.



7.Recommendations

- Determine if online non-compliant products carry any extra risk to the user

It has already been recommended that the products be submitted for analysis to further determine if products that have been produced without notification are made to a lesser standard. The results of such tests can be cross-referenced where notifications have been made to ensure the validity of those notifications.

- Investigate measures to prevent non-compliant e-cigarettes devices and component parts reaching UK marketplace/consumers
- Determine if non-compliant products bear any greater risk (i.e. are lesser quality component parts used as under regulation)
- Work with Primary Authorities for large internet retailers/auction sites to develop systems to prevent online sales of non-compliant product

In respect of devices it is apparent that a number of devices are reaching consumers via the online market, although it is not exclusively online, the searchable nature of the internet makes it easier for a consumer wishing to find non-compliant products (e.g. a 4ml tank) to find said item for sale. More work needs to be done to prevent the products reaching the UK market, however additional work is recommended to determine if the products in question carry any greater risk than a fully notified product.

- Consider 2ml capacity limit of devices

It would be beneficial for further expert opinion on the validity of the 2ml capacity as it is clear from availability that there is user demand for higher capacity, yet unclear where the consumer risk lies in respect of a larger tank size.

Acknowledgements

I would like to thank Jane Macgregor of the Chartered Trading Standards Institute for her assistance and co-ordination of this project.

Appendix – Results Table

Product	Price Paid	Instructions	Batch Code	Tamper Proof	EU Address	Health Warning	Size	Strength
Device 1	£16.98	x	x	x	x	x	3.5ml	n/a
Device 2	£29.99	y	x	y	x	x	4ml	n/a
Device 3	£7.50	x	x	x	x	x	1.6ml	n/a
Device 4	£3.99	x	x	x	x	n/a	n/a	n/a
Device 5	£9.99	y	x	y	x	x	4ml	n/a
Device 6	£36.99	y	VV20171130	y	y*	y*	8ml	n/a
Device 7	£5.99	y	x	y	x	x	4ml	n/a
Liquid 01	£2.99	x	07CHOCO	x	y	x	10ml	6mg
Liquid 02	£1.59	y	7132E	y	y	y	10ml	18mg/ml
Liquid 03	£3.25	y	02/2017/8F48	y	y	y*	10ml	18mg/ml
Liquid 04	£8.65	x	x	y	x	x	30ml	3mg/ml

Liquid 05	£8.98	x	x	y	y	x	10ml	24mg/ml
Liquid 06	£11.99	x	x	y	y	n/a	120ml	0mg/ml
Liquid 07	Free	y	B5703	y	y	y	10ml	18mg/ml
Liquid 08	£6.99	x	#####	y	y	x	10ml	3mg/ml
Liquid 09	£11.74	x	x	x	x	n/a	50ml	0mg/ml
Liquid 10	Free	y	145324F	y	y	y	10ml	18mg/ml
Liquid 11	£3.45	x	date	y	y	y	10ml	3mg/ml
Liquid 12	£3.00	x	x	x	x	x	10ml	9mg/ml
Liquid 13	£2.50	y	27.05.17	x	y	y	10ml	3mg/ml
Liquid 14	£3.99	y	MW001	x	y	x	10ml	3mg/ml
Liquid 15	£9.99	y	MJ002	y	y	y	3x10ml	3mg/ml
Liquid 16	£6.99	x	02-Jun-19	y	y	x	10ml	3mg/ml
Liquid 17	£0.99	x	04/25/2016	y	x	x	10ml	12mg/ml
Liquid 18	£7.95	y	2.71E+08	y	y	y	10ml	6mg/ml
Liquid 19	£5.99	y	y	y	y	y	10ml	18mg/ml

Liquid 20	£5.99	y	y	y	y	y	10ml	6mg/ml
Liquid 21	£7.99	x	00-01452	y	x	x	30ml	3mg/ml *
Liquid 22	£16.99	x	00-01452	y	x	x	30ml	18mg/ml
Liquid 23	£5.99	x	x	x	y	x	30ml	72mg/ml
Liquid 24	£12.41	x	FF050918	x	x	x	50ml	6mg/ml
Liquid 25	£6.28	x	x	y	x	x	50ml	6mg/ml
Liquid 26	£4.59	x	x	y	x	x	32ml	3mg/ml
Liquid 27	free	x	x	y	x	x	10ml	6mg/ml