CHAPTER 8 – UK GOVERNMENT INTERPRETATION OF THE REQUIREMENTS FOR LABELLING E-LIQUIDS FOR NI

SUBMISSION OF NOTIFICATIONS FOR NOTHERN IRELAND UNDER ARTICLE 20 OF DIRECTIVE 2014/40/EU

INTRODUCTION

Several queries have been raised with the Department of Health and MHRA, concerning the labelling provisions of the Tobacco Products Directive (TPD) and how these should be applied to bottles of e-liquid. Given the limited space available on packs and that the text of the Directive is open to interpretation, please find below clarification on the UK Government’s interpretation of the requirements. Please ensure you read the accompanying notes.

TPD Article 20(4)(b) requires certain information to appear on the ‘unit packets’ and any ‘outside packaging’ of electronic cigarettes and refill containers. The UK implementing regulations transpose the definitions of ‘unit packet’ and ‘outside packaging’ as:

a “**unit pack**”, in relation to a tobacco product or related product, means the smallest individual packaging in which that product is, or is intended to be, presented for retail sale (regardless of whether it is presented inside a container pack), but does not include any transparent wrapper.

a “**container pack**”, in relation to a tobacco product or related product means any packaging—

(a) in which that product is, or is intended to be, presented for retail sale; and

(b) which contains (whether fully or partially enclosing)—

(i) a unit pack of that product, or

(ii) an aggregation of such unit packs,

and where there is more than one separate layer of such packaging, each layer is to be regarded as a separate container pack, but a transparent wrapper alone is not a container pack.

The principle that underpins the legislation is that the consumer receives the required information before purchasing. To aid understanding a number of scenarios are explored below:

1) Bottle of e-liquid with no further packaging other than an information leaflet attached to the bottle via tag or other means

The labelling requirements must be applied to the bottle, via label, pull-out label or other means.

2) Bottle of e-liquid and information leaflet placed within a cardboard box/sleeve

The cardboard box/sleeve is considered the smallest individual packaging. TPD labelling must be applied to the cardboard box/sleeve. The bottle does not have to carry this information. Producers will wish to include information on the bottle to identify the product and ensure it can be used safely.

3) Multipack of 2 or more bottles of e-liquid or e-liquid included in a presentation box or starter kit

If the individual bottles are placed in a cardboard box/sleeve (as in point 2) TPD labelling must be applied to both the individual cardboard box/sleeve and each subsequent layer of packaging (container pack).

Where the individual bottles not packaged and are aggregated in a multipack or presentation box, the multipack or presentation box would be considered the unit pack. In this scenario only the multipack or presentation box would require TPD labelling. Producers will wish to include information on the bottle to identify the product and ensure it can be used safely.

**Notes:**

• When applying the health warning producers must adhere to the provisions on format and positioning in TPD Articles 9(4) and 12(2)

• This guidance only relates to the TPD labelling requirements and no other statutory requirements such as European Regulation (EC) No 1272/2008 on classification, labelling and packaging of chemical substances (CLP).

• All the above examples apply equally to other forms of nicotine refill containers such as nicotine-containing cartridges.

Further information and guidance on the regulation of e-cigarettes is published on the [Medicines and Healthcare products Regulatory Agency (MHRA)](https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products) websites.

Further information and advice on labelling on CLP can be obtained from the Health and Safety Executive [www.hse.gov.uk](http://www.hse.gov.uk)

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