

## CHAPTER 1 – SUBMISSION TYPE

### INTRODUCTION

Part 6 of the Tobacco and Related Products Regulations 2016 (TRPR)an obligation on the manufacturers and importers of electronic cigarettes to submit a notification of such products they intend to market.

The European Commission has established a common format for the notification of these products within Commission Implementing Decision 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers. The submission format is set out in the annex to that Decision and the submission type is required in section 2 of that annex. The UK will remain in alignment with the common format set out in the annex.

### WHAT IS REQUIRED

Regulation 31 of the TRPR requires the manufacturer or importer of an electronic cigarette or refill container to submit a notification for all products to be placed on the market.

A new notification is required for each substantial modification of the product.

### INFORMATION TO BE REPORTED

- 1 Notification of a new product (6 months advance notice, new EC-ID number).
- 2 Substantial modification of information on a previously notified product (6 months advance notice, new EC-ID number with a link to the previous EC-ID)
- 3 Update of existing product – addition of information in section 3.B on product format notified (new EC-ID version).
- 4 Update of existing product – withdrawal of information in section 3.B on product notified (new EC-ID version. To note: This may include withdrawal of a product or a product format.
- 5 Update of existing product – other information (new EC-ID version)
- 6 Updates to information to be submitted annually under Regulation 32 of TRPR. (new EC-ID version)
- 7 Correction (new EC-ID version)

Submission types 1 & 2- new notifications or substantial modifications to previously notified products:

#### Submission type 1

- This submission type should be chosen when notifying all new e-cigarettes and refill container products. Such a notification must be made at least 6 months before the intended date of placing on the market.

## Submission type 2

This submission type should be chosen when a substantial modification is made to a previously notified product. This notification must be made at least 6 months before the intended date of placing on the market. A substantial modification is a change to the product that may have an effect on the human body. Such changes include one or more of the following:

o any change to the qualitative or quantitative composition of the nicotine-containing liquid

o any change to the volume of a refill container, tank or cartridge

o any change to the composition, design or power output of a device which would be likely to affect emissions

Submission types 3, 4 & 5 - Manufacturers and importers should update their notification and choose an appropriate submission type from the list below when doing so:

## Submission type 3

(This concerns the addition of information in Section 3.B only.)

## Submission type 4

(This concerns the withdrawal of information in Section 3.B only.) This submission type should be chosen if a product, or an individual product format, is to be withdrawn from the market. This update should be made promptly to ensure proper market oversight, e.g. that ongoing fees are not charged for the notification.

## Submission type 5

(This concerns updates to information in sections other than the addition of information in Section 3.B.) This submission type should be chosen when updates to sections other than Section 3.B are required but the change is not a substantial modification (see submission type 2 above).

## Submission type 6 – updates to information to be submitted annually under Regulation 32 of TRPR

This information includes annual reports on sales volume, by brand name and type of product and the mode of sale of the products. Where available, this report should also include information on the main types of current users and the preferences of various consumer groups including young people and non-smokers and executive summaries of any market surveys carried out on these.

## Submission type 7 – Correction

This submission type should be chosen in order to rectify errors in previously submitted information (such as typos, spelling corrections etc.)