SUBMISSION OF NOTIFICATIONS UNDER PART 6 OF THE TOBACCO AND RELATED PRODUCTS REGULATIONS 2016

INTRODUCTION

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

Regulation 32 requires manufacturers and importers to submit annual reports on sales of their notified products.

Regulation 32 states the following:

(1) A producer of electronic cigarettes or refill containers must submit the following information to the Secretary of State—

(a)comprehensive data on the producer’s sales volumes in the United Kingdom, by brand and variant name;

(b)any information available to the producer, whether published or not, on the preferences of consumer groups in the United Kingdom, including young people, non-smokers and the main types of current users;

(c)the mode of sale of the producer’s products in the United Kingdom; and

(d)executive summaries of any market surveys carried out by the producer in respect of paragraphs (a) to (c).

**GB ANNUAL REPORTING REQUIREMENTS**

Reports should be submitted each year by 20 May. The report should cover the whole of the preceding calendar year.

**WHAT TO INCLUDE IN ANNUAL REPORTS**

The following information must be provided:

**Product EC-ID or GB-ID** – the ID of each product being reported on. Where a product has been modified and this has resulted in a new ID number, the report for previous variants can be added under the current ID number if preferred, rather than reporting each separately.

**Product type –** as declared on the notification.

**Brand** – each brand variant on the notification should be listed separately.

**Mode of sale** – Please indicate the type of retail arrangement, for example internet only, retail shops, etc.

**Sales volumes** – these should be provided separately for each brand variant if possible. Where e-cigarette products are sold in different pack sizes (for example a pack containing a single product unit or a pack of three product units), please calculate the total number of units of the product sold and report that.

For refill containers, the sales data should be provided as a total volume sold in millilitres (ml).

**Market surveys** – a summary of the findings of any market surveys undertaken during the reporting period.

**Additional information –** This includes any information held about the main types of current users during the reporting period and the preferences of various consumer groups.

**Details of the submitter company and contact details for any enquiries** - this is not required if it is the same as the company contact details recorded on the MHRA portal.

**HOW TO SUBMIT ANNUAL REPORTS**

UK sales figures can be submitted via the MHRA portal in the third tab which is the Product Presentation (please see User Guidance). Additionally, you may choose to send your annual sales data directly to the TPD Notifications team via email using a simplified excel template which allows you to report across a range of products.

Any additional information required such as summaries of market surveys or consumer preferences can be attached to the email as a PDF file. If you require a copy of this Annual Sales template please send a request to [TPDnotifications@mhra.gov.uk](mailto:TPDnotifications@mhra.gov.uk) . Please note this is the same email address the report should be returned to on completion.

If you have completed the MHRA spreadsheet to cover all your products, you can submit this spreadsheet for each EC-ID without amendment. Alternatively, individual sheets can be produced for each product and uploaded onto the MHRA portal with any additional information required.

**CONFIDENTIALITY**

MHRA is subject to the Freedom of Information Act but its view is that all annual reports submitted under regulation 32 are commercially confidential. We will not publish individual reports but may in the future make aggregated information available in a format where sales of individual products and companies are not identifiable.

**MHRA March 2022**