

UK DISCUSSION PAPER ON SUBMISSION OF NOTIFICATIONS  
UNDER ARTICLE 20 OF DIRECTIVE 2014/40/EU

CHAPTER 7 – ADVICE ON SUBMITTING ANNUAL REPORTS FOR  
ELECTRONIC CIGARETTES AND REFILL CONTAINERS

**INTRODUCTION**

Article 20(2) of Directive 2014/40/EU [TPD] places an obligation on the manufacturers and importers of electronic cigarettes to submit a notification to the competent authorities of the Member States of such products they intend to market.

Article 20(7) of the TPD requires manufacturers and importers to submit annual reports on sales of their notified products.

Article 20(7) states the following:

“Member States shall require manufacturers and importers of electronic cigarettes and refill containers to submit, annually, to the competent authorities:

- (i) comprehensive data on sales volumes, by brand name and type of the product;
- (ii) information on the preferences of various consumer groups, including young people, non-smokers and the main types of current users;
- (iii) the mode of sale of the products; and
- (iv) executive summaries of any market surveys carried out in respect of the above, including an English translation thereof.

Member States shall monitor the market developments concerning electronic cigarettes and refill containers, including any evidence that their use is a gateway to nicotine addiction and ultimately traditional tobacco consumption among young people and non-smokers.”

Article 20(8) states that:

“Member States shall, upon request, make all information received pursuant to this Article available to the Commission and other Member States. The Member States and the Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.”

The European Commission has established a common format for the notification of these products within [Commission Implementing Decision \(EU\) 2015/2183](#) of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers. The annex to that Decision does not include a format for the information required in the annual report but there is a facility to upload individual reports onto the EU-CEG portal. The submission type for this action is not yet fully operational.

## UK ANNUAL REPORTING REQUIREMENTS

Article 20(7) of the TPD has been implemented in the UK by means of [regulation 32](#) of the Tobacco and Related Products Regulations 2016. The first annual report for UK sales must be submitted by 20 May 2017. It should cover the period from 20 May 2016 to 31 December 2016.

If companies had products on the market before 20 May 2016, it is an acceptable alternative to provide a report covering the whole of 2016 if this is easier.

From 2018, a report 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** – the EC-ID of each product being reported on. Where a product has been modified and this has resulted in a new EC-ID number, the report for previous variants can be added under the current EC-ID number if preferred, rather than reporting each separately.

**Product type** – as declared on the notification (see [guidance](#)).

**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 EU-CEG.

## **HOW TO SUBMIT ANNUAL REPORTS**

Individual sales figures can be submitted on the EU-CEG portal. MHRA has also decided to provide a simplified format for reporting across a range of products as an additional option. This is intended to facilitate data submission by companies and data analysis by the UK competent authorities, MHRA and Public Health England.

MHRA has published a spreadsheet template for submission of data. One spreadsheet can be used to report on all your products and emailed to [TPDnotifications@mhra.gov.uk](mailto:TPDnotifications@mhra.gov.uk). 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 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 EU-CEG portal with any additional information required. If you use the portal option, we would be grateful if you would also send an email with copies of all the information to [TPDnotifications@mhra.gov.uk](mailto:TPDnotifications@mhra.gov.uk).

## **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. Reports may be shared with the Commission and other competent authorities under the TPD, on this confidential basis. 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/UK**