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

CHAPTER 7 – GENERAL ADVICE ON VIGILANCE - ELECTRONIC CIGARETTES DEVICES AND REFILL CONTAINERS

INTRODUCTION

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

The Tobacco and Related Products Regulations 2016 (TRPR) implement the TPD in the UK. Regulation 39 of the TRPRs sets out the vigilance requirements for producers of e-cigarettes and e-liquids (refill containers). This requires that the producer must establish and maintain a system for collecting information about all of the suspected adverse effects on human health of the product.

Where the producer has reason to believe that an electronic cigarette or refill container which it intends to or has supplied, is not safe, not of good quality or fails to conform with Part 6 of the Regulations, they must (as appropriate):

(a) immediately take the corrective action necessary to bring the product into conformity with Part 6 of the Regulations;

(b) withdraw the product;

(c) recall the product.

They must immediately inform MHRA (and the competent authority of any other member State in which the product has been supplied or is intended to be supplied), giving details of:

(a) the risk to human health and safety;

(b) any corrective action taken; and

(c) the results of any corrective action taken.

Regulation 37 requires that each unit packet of the electronic cigarette or refill container must include a leaflet with information on … contact details of the producer; and if the producer is not based in a member State, a contact person within a member State.

PRACTICAL ADVICE ON COMPLIANCE

Information that may impact on the safety, quality or compliance of a product may come in various forms including reports of adverse effects from users, complaints about the product from retailers or customers, internal quality testing results and other sources.
You must have an address in the EU where you are responsible for receiving this information and details of how to contact you must be included on the leaflet of each product sold (or on the label if there is no leaflet).

When information is received, this should be reviewed promptly in order to consider if it suggests any problems with your product and if any action is required to protect public health. New reports should be correlated with previous information to see if any pattern is emerging. It is considered good practice to follow up with reporters of adverse events/product complaints (where permission has been given) to obtain further event/product details.

You should maintain records of:

- customer complaints and outcomes, including any corrective action required
- adverse event reports, tracking and outcomes, including any corrective action required
- safety reports/ongoing screening, including any corrective action required

Although you hope it will never be used, you will need to develop and test procedures to quarantine products, to contact your customers and users to seek withdrawal or recall of products supplied.

If action is required, you must implement this promptly and tell MHRA by email to TPDsafety@mhra.gov.uk. The email should give details of the problem and steps taken to manage this.

MHRA ACTIONS

Each report of a safety concern submitted to the MHRA by suppliers is reviewed and the corrective action assessed to evaluate the suitability of the action. The MHRA may then request further information regarding the safety concern or further action to be taken to minimise risk to public health.

The MHRA collate suspected adverse event reports reported via the Yellow Card Scheme (https://yellowcard.mhra.gov.uk/). Ongoing review of these reports is undertaken to detect potential safety concerns. Where a report has been made for an identifiable product or manufacturer, the MHRA will share an anonymised copy of the report with the supplier. This report must then be recorded in their vigilance system. All adverse event reports associated with e-cigarettes will be followed up (where permission has been granted by the reporter) for additional information. If additional information is received this will also be shared with the supplier.

Information received by the MHRA is reviewed alongside other safety data which may include published literature and other sources of information to determine whether there is a risk to human health and the seriousness of this risk.

Where a safety risk has been identified and validated using established vigilance procedures, the MHRA will inform the company of the identified risk and immediate corrective action must be taken in accordance with the requirements set out by the MHRA and regulation 39 of the TRPR.