

Paper for Information - TOX/2020/07

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT (COT)

Paper for Information: Potential toxicological risks from electronic nicotine (and non-nicotine) delivery systems (E(N)NDS – e-cigarettes). Data from MHRA Yellow Card Scheme

Introduction

1. This paper has been prepared for information to support the ongoing consideration of the potential toxicological risks associated with electronic nicotine delivery systems (ENDS) and electronic non-nicotine delivery systems (ENNDS) (collectively abbreviated to E(N)NDS). It provides an update on Yellow Card Scheme reports for ENDS products and also additional vigilance reporting requested by MHRA.

Yellow Card Scheme data

2. [The Yellow Card scheme](#) is a mechanism by which suspected problems or adverse incidents with medicines or medical devices can be reported. Anyone can report a problem through the scheme.

3. Issues relating to E(N)NDS can also be reported through the scheme. With implementation of the [Tobacco and Related Products Regulations](#) on 20th May 2016, MHRA became the competent authority enforcing the rules on e-cigarettes and their refills in the regulations. At that point safety concerns from healthcare professionals and the public were formally collected through the Yellow Card scheme. The reports received from 20th May 2016 until 9th January 2020 are attached in Annex A.

4. Even before implementation of the Tobacco and Related Products Regulations, some Yellow Card reports were received for ENDS in the absence of any other means of reporting issues. These are reported separately in Annex B.

5. The Committee has previously noted that it would be helpful to have a comparator for the Yellow Card reports for E(N)NDS, and as such reports for nicotine replacement therapy, bupropion and varenicline from 1st January 2010 to 31st December 2019 are provided in Annex C.

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6. Guidance on interpretation of the e-cigarette and smoking cessation product reports is provided in Annex D.

Other MHRA vigilance

7. In addition to Yellow Card reports, ENDS producers are required to establish and maintain vigilance systems. In October 2019, MHRA requested vigilance data from all producers relating to respiratory reactions associated with ENDS. These data are presented in Annex E.

PHE COT Secretariat
January 2020

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Paper for Information - TOX/2020/07 – Annex A

**COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS
AND THE ENVIRONMENT (COT)**

**Potential toxicological risks from electronic nicotine (and non-nicotine)
delivery systems (E(N)NDS – e-cigarettes). Data from MHRA Yellow Card
Scheme**

Drug Analysis Print of e-cigarette Yellow Card reports since Tobacco and Related
Products Regulations

**PHE COT Secretariat
January 2020**

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Paper for Information - TOX/2020/07 – Annex B

**COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS
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**Potential toxicological risks from electronic nicotine (and non-nicotine)
delivery systems (E(N)NDS – e-cigarettes). Data from MHRA Yellow Card
Scheme**

Drug Analysis Print of e-cigarette Yellow Card reports before Tobacco and Related
Products Regulations

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Paper for Information - TOX/2020/07 – Annex C

**COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS
AND THE ENVIRONMENT (COT)**

**Potential toxicological risks from electronic nicotine (and non-nicotine)
delivery systems (E(N)NDS – e-cigarettes). Data from MHRA Yellow Card
Scheme**

Drug Analysis Print of Nicotine Replacement Therapy, Bupropion and Varenicline

**PHE COT Secretariat
January 2020**

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Paper for Information - TOX/2020/07 – Annex D

**COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS
AND THE ENVIRONMENT (COT)**

**Potential toxicological risks from electronic nicotine (and non-nicotine)
delivery systems (E(N)NDS – e-cigarettes). Data from MHRA Yellow Card
Scheme**

Interpretation guides to detailed e-cigarette analysis print and detailed drug analysis
print

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January 2020**

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Paper for Information - TOX/2020/07 – Annex E

**COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS
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**Potential toxicological risks from electronic nicotine (and non-nicotine)
delivery systems (E(N)NDS – e-cigarettes). Data from MHRA Yellow Card
Scheme**

Vigilance data requested by MHRA from e-cigarette producers on respiratory reactions

This information is attached, it has been received by the Committee as pre-publication data and is not publicly available. The data will be published by the MHRA in due course.

**PHE COT Secretariat
January 2020**