Medicines & Healthcare products Regulatory Agency

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MHRA Website

[redacted]

Our Ref: **FOI2024/00769**

7 January 2025

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 4 December. You wrote:

> *I am trying to find out how many reports per year have been submitted to the yellow card scheme about e-cigarettes.*
>
> *Currently I can find up to date (April 2024) information in this table Electronic_Cigarette_Drug_Analysis_Print_up_to_31.03.2024.pdf<https://assets.publishing.service.gov.uk/media/661fe3fdced96304c8757f5c/Electronic_Cigarette_Drug_Analysis_Print_up_to_31.03.2024.pdf> – however this is not broken down by year or into how seriously the reports were considered by the MHRA.*
>
> *This information would be really useful – the most up to date data I can get for this comes from the OHID report 'Nicotine vaping in England: 2022 evidence update summary' – it would be excellent if I could access the data on the total of reports each year and how serious said reports are considered (updated up to 2024 as the table above is).*
>
> *This is the section in the OHID report which references MHRA data:*
> *Between 20 May 2016 (implementation of TRPR) and 13 January 2022, MHRA received 257 reports of adverse reactions (26 of those since January 2021). Each report represents an individual for whom more than one adverse reaction could have been reported. A report is not proof that the reaction was caused by a vaping product, just that the reporter thought it might have been.*
> *Since January 2021, the MHRA has considered 14 of the reports as serious and no fatalities were reported.*
>
> *Please can you direct me to where I can access this information but up to date for 2024?*

MHRA Response

We confirm that we hold the information you have requested and provide it below. I can confirm that up to and including 31st December 2024, the MHRA received 372 suspected adverse reaction (ADR) reports associated with nicotine-containing e-cigarettes through the Yellow Card scheme. The attached e-cigarette Drug Analysis Print (DAP) provides a breakdown of the 372 suspected ADR reports.

When considering this data, it is important to be aware that reporters are asked to submit Yellow Card reports even if they only have a suspicion that an e-cigarette may have caused an ADR. Many factors including underlying or previously undiagnosed illness unrelated to an e-cigarette must be considered when assessing whether an e-cigarette has caused an ADR. Further details on interpreting the DAP can be found in the accompanying E-Cigarette Analysis Print interpretation guide.

A summary of all suspected adverse reactions associated with nicotine-containing e-cigarettes reported through the Yellow Card scheme can also be viewed on our e-cigarette Analysis Print. Please refer to the accompanying guidance document for information on how this data should be interpreted.

Furthermore, you will note that the number of reports provided here is less than the number of reports included in the print currently published. The MHRA database is dynamic in nature and data is correct at the time of provision. Upon review of the differences seen it has been noted that some duplicate reports may have been merged or reports have been nullified at the request of the reporter.

You also asked for the numbers of these reports that were classified as serious. A Yellow Card report is considered serious according to two criteria; firstly, a reported reaction can be considered serious according to our medical dictionary if the reported reaction is considered serious. Secondly, a Yellow Card can be considered serious if the original reporter considers the report to be serious, whereby they can select based on 6 criteria[1]. Based on these criteria, 152 of the reports were considered serious. Please find attached Annex A which displays Table 1, containing a breakdown of the total number of ADR reports associated with nicotine-containing e-cigarettes through the Yellow Card scheme per year, including seriousness, up to and including 31st December 2024.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make

[1] The seriousness criteria for ADR reporting were determined by a working group of the Council for International Organizations of Medical Sciences (CIOMS) and are defined as 6 possible categories which are documented on the Yellow Card. Reporters can select one or more of the following criteria by ticking the appropriate box on the Yellow Card. The criteria are: (1) patient died due to reaction (2) life threatening (3) resulted in hospitalisation or prolonged inpatient hospitalisation (4) congenital abnormality and (5) involved persistent or significant disability or incapacity or (6) if the reaction was deemed medically significant.

a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.