Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

15 June 2023

FOI 23/292

Dear [redacted]

Thank you for your information request, dated **18/04/2023.** I have provided a response to your specific questions below:

"How many vape products have you approved for market in 2022 and how does that compare to previous year? How many so far this year? And what are the success rates for approval?"

The number of vape products published in 2022 were 11598, as compared to 3894 in 2021. In 2023, we have currently published 5843 notifications. 500 out of 6343 assessed notifications between 1/1/23 to 30/4/23 have required corrective action, which equates to a 92.1% success rate during this period.

"**In the last year have you introduced any changes to what you want vape companies to submit as part of the product notification process?"**

No, these requirements are defined by the legislation which is controlled by the Office of Health Improvement and Disparities (OHID).The MHRA has published guidance updates for industry to improve the quality of data submitted by producers, and will continue to do so during 2023.

"Are you looking at any changes to what you want vape companies to submit as part of the product notification process?"

The MHRA will be providing guidance to industry in 2023 to specify vigilance and production data to be submitted under "production files".

"What are the most and least common compliancy breaches observed by the MHRA?"

The common causes for notifications to fail compliance checks are:

- Incomplete/insufficient toxicology data
- Missing UK address
- Incomplete/insufficient nicotine uptake/consistency documentation

“What, if anything, are you looking to introduce in the future by way of product data and other information required by vape manufacturers to submit as part of the product notification process in order to enhance quality and safety standards across the industry.”

The MHRA are currently assessing a number of potential enhancements to the MHRA Submission Portal, MHRA Webpages, Published Guidance and stakeholder engagement. However, changes to the notification requirements will require legislative amendment or primary legislation which is controlled by OHID.

“Are you/have you made any additional investment in resources to help support vape product compliance with the regulations - if so, how many new staff and what roles are they performing?”

The MHRA has recruited a third full time notification assessor and are currently recruiting a fourth full time notification assessor. In addition, the MHRA has also recruited an E-cigarette Compliance Co-ordinator to provide a dedicated resource for the management of regulatory referrals, enforcement requests and evidence-based project work.

“What types of investigations have you carried out on vape companies without naming any businesses?”

The MHRA assist regulatory enforcement agencies investigating cases of post-notification non-compliance to provide and review intelligence referrals, evidence packages and witness statements. The MHRA does not have enforcement powers under the Tobacco and Related Products Regulations 2016. Where a submitter is based outside of the UK the MHRA will engage with the manufacturers and share our findings/corrective actions with Trading Standards to enable further investigation/enforcement to be taken against the UK responsible persons under the regulations.

“Do you get any third-parties flagging up potentially non-compliant vapes post-approval? Have you any data for last couple of years? If so, what percentage of these cases have you been able to look into.”

Please be aware that the MHRA and Trading Standards authorities have a duty to investigate alleged offences under Part 9 of the Tobacco and Related Products Regulations 2016 (as amended). For the above request:

Medicines & Healthcare products
Regulatory Agency

The information requested cannot be provided under the Freedom of Information Act for the following reason:

- *'Information received* is exempt from release under Section 30 - **Investigations** – this exempts information if it has at any time been held by the authority for the purposes of any investigation which the public authority has a duty to conduct.
- Discloser of information should not undermine the investigation, prosecution or prevention of crime, or the bringing of civil or criminal proceedings by public bodies. The investigation and prosecution of crime involve a number of essential requirements. These include the need to avoid prejudicing effective law enforcement, the need to maintain the independence of the judicial and prosecution processes, and the need to preserve the criminal court as the sole forum for determining guilt.

We are unable to respond to the questions below as the information is not held by the MHRA:

- How many prosecutions did you undertake in the vape sector in 2022 and has that been rising compared to 2021? What is the picture so far in 2023?
- What are they breaches that relate to these prosecutions?
- How many investigations did you carry out on vape businesses in 2022 relating to the quality and safety of their products? How does this compare with 2021 and what does the picture look like for 2023 so far.
- How many prosecutions in 2022 were successful and how did this compare to 2021?
- What was the level of financial penalties did you hand out in 2022 for vape companies who were in breach of regulations and how this compare to 2021?
- How much was the largest penalty and what did this relate to (without naming the business)

You may be able to contact the relevant lead enforcement authorities who may be able to provide the data you require. The appropriate agency will be dependent on the offence data required and vaping related legislation in question. This could include:

- Trading Standards – Product Safety and Underage Sales
- Border Force – Importation of Illicit goods
- The Advertising Standards Agency – Advertising
- The Health and Safety Executive – Chemical Labelling and Classification
- The Office of Product Safety and Standards – Batteries
- The Environment Agency – Electrical Waste

Medicines & Healthcare products
Regulatory Agency

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

The Freedom of Information Act only entitles you access to information. The information supplied is subject to Crown copyright, and there are some restrictions on its re-use. For information on the reproduction or re-use of MHRA information, please visit https://www.gov.uk/government/publications/reproduce-or-re-use-mhra-information/reproduce-or-re-use-mhra-information.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

MHRA E-Cigarette Unit