Medicines & Healthcare products Regulatory Agency

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

[redacted]

FOI 23/701

Dear [redacted]

Thank you for your information request, dated **25/09/2023**, where you asked:

“to make a formal request for information under the Freedom of Information Act 2000.

On 17 February 2023 the MHRA E-Cigarette Unit and MHRA Safety and Surveillance Team wrote to Victor Xiao Chief Operating Officer of Elfbar/IMiracle (SHENZHEN) Technology Co Ltd, a letter headlined CORRECTIVE ACTIONS AND WITHDRAWAL OF NON-COMPLIANT ELECTRONIC CIGARETTES.

The letter outlined eight points on which Elfbar was instructed to file extra information by February 24 2023. IT also instructed Elfbar to file a progress report every two weeks until the regulatory non-compliances have been resolved.

I am writing to request copies of the correspondence between Elfbar and the MHRA subsequent to this letter, including all Elfbar's responses to it, MHRA responses to Elfbar, and continuing correspondence until the matter was resolved.”

This information is not subject to the commercial interests exemption under Section 43 of the FOIA 2000 because there is an overwhelming public interest in the disclosure of this information.

The Information Commissioners' Office guidance on the public interest test on its website states that there is a public interest "good decision-making by public bodies", and "ensuring fair commercial competition in a mixed economy."

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The progress of the MHRA's investigation is relevant both to the conduct of the MHRA's investigation into ELFBAR, and the competitive practices employed by Elfbar vis a vis its competitors in the e-cigarette market.

Unfortunately, the information is considered exempt from release under sections:

Section 31 – Law enforcement
Section 31(1)(a) applies when disclosure would be likely to prejudice the prevention and detection of crime , and section 31(1)(g) and 31(2)(a) and (b) when disclosure would be likely to prejudice the exercise by any public authority of its functions for the purposes of ascertaining whether any person has failed to comply with the law and ascertaining whether any person is responsible for any conduct which is improper.

To explain why the exemption applies, information gathered by both the MHRA and Trading Standards is shared between these agencies. This information includes intelligence and evidence that may be used to support enforcement action as part of ongoing or future investigations. The release of this information may prejudice these investigations across any UK local authority considering legal action against UK liable parties (producers), as well as offending businesses involved in the supply and sale of those products.

Section 43 – Commercial interests
This applies when disclosure would be likely to prejudice the commercial interests of any party.

Release of commercially sensitive information would undermine the MHRAs ability engage with manufacturers who are not liable under UK law. As the regulations do not extend to businesses outside of the UK and interaction with the MHRA is voluntary, releasing this information would significantly impair future interactions of this type with non UK submitters. In the event of risk to public health, rather than general compliance the loss of these interactions with non-UK parties could have far reaching implications.

The information you have requested concerns investigations enforced by regional Trading Standards authorities across the United Kingdom which may include information gathered by the MHRA and shared with those enforcement bodies. As a result of the unintended publication of documents by the Chartered Trading Standards Institute sensitive information became available to the public. This was recognised as being published in error and was removed by the institute within 24 hours. In these circumstances, we consider that the information we hold remains sensitive, and that its disclosure would be likely to lead to the prejudice we have described above.

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Section 31 and 43 are qualified exemptions, which means that we have considered whether the public interest in releasing the information is outweighed by the public interest in maintaining the exemptions to withhold the information.

We have weighed the public interest for the exemptions below.

In favour of disclosure, we consider that there is a general public benefit from the maintenance of public confidence in the relevant investigation processes. In this particular case the there are two elements to consider.

1. *"good decision-making by public bodies"*

   Release of this information would demonstrate the value of the MHRAs interactions with Elf's Chinese manufacturer(submitter) in supporting law enforcement investigations, and the scale of corrective action requiring monitoring and interventions by Trading Standards to bring UK liable parties (producer/s) into compliance.

2. *"ensuring fair commercial competition in a mixed economy."*

   Release of this information would demonstrate the willingness of the manufacturers (submitter) to engage in voluntary corrective actions with the MHRA. Legal obligations are placed on the producers under UK regulations, and not the submitter in cases of this type, where the manufacturer (submitter) is not based in the UK.

In favour of maintaining the exemption, the MHRA is committed to working with non-UK manufacturers (around 70% of submitters to the UK) and Trading Standards authorities to achieve regulatory compliance. This is achieved through the assessment and monitoring of corrective actions undertaken by manufacturers and the life cycle of those actions through the supply chain to UK liable parties and on to the retail market. There is a strong public interest in maintaining the effectiveness of the MHRA activities and investigations in this area.

Most importantly, we consider that the strongest public interest lies in protecting against the risk of negatively impacting ongoing and future investigations with Trading Standards authorities and that this outweighs the public interest in disclosure in a case of this type. Therefore, we consider that there is a greater public interest favours in the MHRA maintaining the exemptions in this case.

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.

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If you have a query about the information provided, please reply to this email

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 Customer Experience Centre
Communications and engagement team
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