Medicines & Healthcare products Regulatory Agency

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

4 January 2024

FOI 23/982

Dear

Thank you for your information request, dated 9 June 2023, where you asked:

"I received details from MHRA's FOI team in June of this year after I had asked for enforcement and seizure details covering the last two financial years (up to March 2023). However, the response only appeared to give information on enforcement and seizures from one of those financial years (up to March 2022)... I was wondering if the Newsdesk might have access to the information as it relates to Scotland so that I can find out all enforcements and seizures carried out in the financial year 2022-23 and so far this financial year 2023-24."

I apologise for our delay in responding to your request; this was due to an oversight in handling when the request was first received.

I am pleased to provide you with the information requested, save where to do so would risk adversely impacting investigations. Please see below:

Within Great Britain, the MHRA's Criminal Enforcement Unit applies relevant sections of the Human Medicines Regulations 2012 on behalf of the Secretary of State for Health and Social Care (with agreements in place with the Scottish and Welsh governments). This includes a function to conduct investigations into potential criminal breaches of the regulations.

In Scotland, between 01/04/2023 and 19/12/2023, the MHRA took enforcement action in 21 cases under the Human Medicines Regulations 2012. This included the seizure of 279,036 doses of medicine not authorised for use in Great Britain.

Similarly, between 01/04/2022 and 29/03/2023, the MHRA took enforcement action in 10 cases, resulting in the seizure of 84,600 doses of unauthorised medicine.

These seizures comprised a variety of medicine-types including those typically used in the treatment of erectile dysfunction, acne, aiding wakefulness, and pain relief.

Currently, the MHRA is conducting several active investigations into the suspected sale or supply of falsified and unauthorised medicines in Scotland. Due to the status of these investigations, we have chosen to withhold any further details.

Section 30(1)(a)(i) of the Freedom of Information Act 2000 (the Act) provides for exemption from disclosure of information held by a public authority for the purpose of any investigation which the authority has a duty to conduct with a view to it being ascertained whether a person should be charged with an offence.

Section 31(1)(a) of the Act provides for an exemption from disclosure of information which would prejudice the prevention or detection or crime. A further exemption from disclosure can be found at section 31(1)(b), which relates to information that would prejudice the apprehension or prosecution of offenders.

The application of section 30 and 31 exemptions are subject to a public interest test. In considering whether to disclose information relating to these investigations, we have weighed the public interest in disclosure against the public interest in maintaining the exemption.

The factors we consider weigh against disclosure at this time include:

- a) The likelihood of negatively impacting numerous active investigations, including the gathering of evidence and apprehension or prosecution of offenders.
- b) Potentially impairing the detection and prevention of crime by discouraging those who may have provided information, or are considering providing information, from further engagement with the MHRA.
- c) Causing anxiety to those who may have provided information to the MHRA with a reasonable expectation of privacy.

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If you have a query about the information provided, please reply to this email. Please note that the 'FOI Policy' email address that you have previously used is no longer active; please direct FOI correspondence to info@mhra.gov.uk.

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: <u>info@mhra.gov.uk</u>

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,

Criminal Enforcement Unit - Bureau Team Leader

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