

Medicines & Healthcare products Regulatory Agency

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

20 May 2024

MHRA reference: FOI2024/00052

Dear

Thank you for your information request, which we received on 23 April. You asked for:

Under the UK freedom of information act, I'd like to request a summary of the batch and/or serial numbers for Ozempic, Wegovy and Rybelsus that have been banned from entering the United Kingdom on the basis that said drugs carrying those batch/serial numbers are likely to be counterfeit.

To give you an example of what I'm looking for, Ukraine's health ministry has said it banned Ozempic with the batch number MP5B060 (of various dosages and release forms) on the basis it is falsified and has signs of falsification, as well as MP5E511 and NP5G866.

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

We confirm that we hold the information you have asked for, and we are disclosing this information in full.

This information is provided below.

The MHRA enforces the Human Medicines Regulations 2012 on behalf of the Secretary of State for Health and Social Care.

Counterfeit medicines are often defined as medicines made by someone other than the genuine manufacturer, by copying or imitating an original product without authority or rights. Counterfeit medicines infringe trademark law and therefore may



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not fall within the scope of the MHRA Criminal Enforcement Unit. We have interpreted this request as an enquiry about falsified medicines which are fake medicines that are intended to mimic genuine medicines.

The MHRA is not aware of any falsified Wegovy or Rybelsus products circulating in the UK.

Falsified Ozempic products have been detected in the UK, although none have been seized in 2024.

The MHRA has not banned any of the medicines mentioned in this request from entering the UK. The batch numbers previously associated with falsified products are also found on genuine products, therefore their detection has relied upon anomalies not associated with legitimate stock. This has included differences in the colour and construction of the pens, and issues with labelling.

We hope this information is useful for you.

This concludes our response to your request.

If you have a query about this response, please contact us at

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

#### Criminal Enforcement Medicines and Healthcare products Regulatory Agency

#### **Appeal rights**

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: <u>foi.request@mhra.gov.uk</u>

If you remain dissatisfied with the outcome of the internal review, you 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 a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: <a href="https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/">https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/</a>

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF



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