



Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of
Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk

[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2024/00325**

8 August 2024

Dear [REDACTED],

Thank you for your Freedom of Information (FoI) requests:

MHRA Response

We can confirm that we hold the information falling within the description specified in your request.

Section 12(4) of the FoI Act and also the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 provides that requests can be aggregated for the purpose of estimating whether the cost limit applies, providing they relate to any extent to the same or similar information and the requests are received from the same individual or different persons who appear to the public authority to be acting in concert or in pursuance of a campaign.

This is where more than one request has been made within 60 consecutive working days relating to the same or similar information and the requests have been made by the same person [or separate persons acting in concert]. This includes adding to the estimated costs of complying with a later request, the cost of complying with a request that has already been answered. We have therefore aggregated the following requests under this provision:

On 2 July you wrote:

FOI2024/00249

“Under the Freedom of Information Act, I would like to request the following information:

-Since 2019, a list of all instances of detainment of units of injectable medicines labelled as containing semaglutide, including where they were detained, the date of detainment, country or region of origin of the medicines, the importer, the exporter, the medicine's manufacturer, the consignee, the importer, exporter and consignee contact information, the name of the medications, the value or price of the goods, weight/volume and the quantity.

-A copy of export and import certificates for each instance

-A copy of the air waybill for each instance

-A copy of the packaging manifest for each instance

-For each instance, whether any testing was performed to determine the ingredients of these injectable medicines, and the results of such investigations

*-For each instance, whether they were determined to be genuine Ozempic or Wegovy from Novo Nordisk or were falsified semaglutide
I would like you to provide the information in an electronic format."*

On 2 July you wrote:

FOI2024/00250

*"Under the Freedom of Information Act, I would like to request the following information:
-Since 2019, a list of all instances of detainment of units of tablets or pill medicines labelled as containing semaglutide, including where they were detained, the date of detainment, country or region of origin of the medicines, the importer, the exporter, the medicine's manufacturer, the consignee, the importer, exporter and consignee contact information, the name of the medications, the value or price of the goods, weight/volume and the quantity".
-A copy of export and import certificates for each instance
-A copy of the air waybill for each instance
-A copy of the packaging manifest for each instance
-For each instance, whether any testing was performed to determine the ingredients of these tablets or pills, and the results of such investigations
-For each instance, whether they were determined to be genuine Rybelsus pills from Novo Nordisk or were falsified semaglutide*

On 12 July you wrote:

FOI2024/00285

*Under the Freedom of Information Act, I would like to request the following information:
-The names of all manufacturers of semaglutide-containing "weight loss" tablets seized in 2023 and they country the manufacturers are based*

On 12 July you wrote:

FOI2024/00291

*Under the Freedom of Information Act, I would like to request the following information:
-The names of all manufacturers of semaglutide-containing "weight loss" tablets seized in 2023 and THE country the manufacturers are based*

On 17 July you wrote:

FOI2024/00304

*"Under the Freedom of Information Act, I would like to request the following information:
- Electronic copies of all written communication since January 2019, either electronic or physical, between the MHRA or its representatives, and China's National Medical Products Administration or its representatives, regarding "semaglutide" or products containing "semaglutide"."*

On 17 July you wrote

FOI2024/00305

*"Under the Freedom of Information Act, I would like to request the following information:
- Electronic copies of all written communication since January 2019, either electronic or physical, between the MHRA or its representatives, and India's Central Drugs Standard*

Control Organisation or its representatives, regarding "semaglutide" or products containing "semaglutide".

On 17 July you wrote

FOI2024/00309

"Under the Freedom of Information Act, I would like to request the following information:

- Electronic copies of all letters since January 2019, either electronic or physical, between the MHRA or its representatives, and IndiaMart or its representatives, regarding "semaglutide" or products containing "semaglutide".*
- Electronic copies of all letters since January 2019, either electronic or physical, between the MHRA or its representatives, and IndiaMart or its representatives, regarding the products "Fitara" or "Orsema"*

On 18 July you wrote

FOI2024/00313

Under the Freedom of Information Act, I would like to request the following information:

- Electronic copies of all letters since January 2019 between the MHRA or its representatives, and the General Administration of Customs of the People's Republic of China or its representatives, regarding "semaglutide" or products containing "semaglutide".*

On 18 July you wrote

FOI2024/00314

Under the Freedom of Information Act, I would like to request the following information:

- Electronic copies of all letters since January 2019 between the MHRA or its representatives, and India's Central Board of Indirect Taxes and Customs or its representatives, regarding "semaglutide" or products containing "semaglutide".*

On 20 July you wrote:

FOI2024/00321

"Thank you for this, however the response to my request is incomplete.

In your response, you said: "As previously provided to you, we hold details for 2023 of six seizures of tablets said to contain semaglutide. We assessed the seizures as being unauthorised medicines. An unauthorised medicine may be a genuine product, but not intended for the UK market, it will not therefore meet the conditions of the license for sale or supply in the UK."

However, in your response, you only provided details about two seizures in 2024 and four seizures in 2023. Can you please provide the information I have requested about the remaining two seizures in 2023, please".

On 20 July you wrote:

FOI2024/00324

"Under the Freedom of Information Act, I would like to request the following information:

-All information held about any of the following products or their distribution: Orsema, Fitaro, Semavic, Semagcare”

On 20 July you wrote:

FOI2024/00325

“-All information held about instances of MHRA seizures of any of the following products: Orsema, Fitaro, Semavic, Semagcare

- Information on the country or origin of the seized products, if known*
- An assessment of the value of each seized product, if available*
- Information on the quantity seized, if known*
- All information available about the seized product dosage size, if applicable and available*
- Information on where the seized products were shipped from and transported from, if known*
- Whether the products were marked for personal use, research use or other purposes, if known*
- Whether the seized products were intended to be shipped to consumers in the UK or some other type of organization, if known*
- Whether the products were purchased by consumers or businesses in the UK, if known”*

On 22 July you wrote:

FOI2024/00336

“Under the Freedom of Information Act, I would like to request the following information:

- All information held about MHRA seizures of pens of the product Fitaro (pre-filled syringe) - (2.4mg) on 12/10/2023*
- Whether the products were seized at the UK border or inside the UK, if known*
- An assessment of the value of each seized product, if available*
- Information on where the seized products were shipped from and transported from, if known*
- Whether the products or their shipments were marked for personal use, research use or other purposes, if known*
- Whether the seized products were intended to be shipped to consumers in the UK or some other type of organization, if known*
- Whether the products were purchased by consumers or businesses in the UK, if known*
- Whether the products were sold by an online website, a pharmaceutical company, or an individual, if known”*

On 24 July you wrote:

FOI2024/00343

“Under the Freedom of Information Act, I would like to request the following information:

-The date that the Fitaro (pre-filled syringe) - (2.4mg) pens the MHRA seized on 12/10/2023 were imported into the UK, if known

-The date that the Fitaro (pre-filled syringe) - (2.4mg) pens the MHRA seized on 12/10/2023 arrived at the UK border, if known

-The location where the MHRA seized the pens, if known. If the details are not exact, please provide the best available approximation.

-The number of Fitaro (pre-filled syringe) - (2.4mg) pens originally in the shipments when they first arrived at the UK border, if known. If the details are not exact, please provide the best available approximation.

-If the number of the pens in the shipments when they first arrived at the UK border is different than the number that the MHRA seized, then the country, city and any other available geographic details describing the locations of the other pens, if known. If the details are not exact, please provide the best available approximation.”

Thank you for your Freedom of Information (Fol) request received on 20 July. You wrote:

-All information held about instances of MHRA seizures of any of the following products: Orsema, Fitaro, Semavic, Semagcare

-Information on the country or origin of the seized products, if known

-An assessment of the value of each seized product, if available

-Information on the quantity seized, if known

-All information available about the seized product dosage size, if applicable and available

-Information on where the seized products were shipped from and transported from, if known

-Whether the products were marked for personal use, research use or other purposes, if known

-Whether the seized products were intended to be shipped to consumers in the UK or some other type of organization, if known

-Whether the products were purchased by consumers or businesses in the UK, if known

We estimate that the cost of complying with your aggregated requests would exceed the appropriate limit for central Government, set by regulations at £600. This represents the estimated cost of at least one person spending 3½ working days (equivalent to 24 staff-hours)

in determining whether the Agency holds the information, and locating, retrieving and extracting it.

Under Section 12(4) of the Freedom of Information Act the Agency is not therefore obliged to comply with your requests as we have aggregated the cost of processing them together and as such we will not be processing them any further. The reason we are not able to locate the information within the cost limit is:

The Agency is unable to provide any of the information you seek within the appropriate cost limit as you have asked for information that is contained across multiple systems and the scope of the requests is too wide.

Many of your requests have asked multiple questions and many of these require substantial resources to be diverted to undertake the necessary research and to write back with the information requested.

In several instances, a response to a previous request has immediately generated further enquiries and requests for additional information, creating a continuous cycle of correspondence.

The time taken by numerous members of staff to identify, collect and present the information requested represents a grossly oppressive burden on the organisation. To date, it is estimated that three members of staff have spent more than 48 hours answering this series of requests. This represents a substantial investment in time and causes a strain on the efficient running of the Agency owing to the disproportionate amount of time and resources required to handle the requests, which diverts and distracts those staff away from their core functions within the Criminal Enforcement Unit (CEU).

Additionally, some information is held outside of the CEU, and it has required other members of staff to devote substantial amounts of time gathering information to answer the questions. Whilst the questions asked may be for a legitimate purpose and of genuine public interest, the Agency cannot be reasonably expected to comply with the requests given the cumulative effect of the burden and the impact on the Agency's functions.

The requests have been frequent and multiple similar requests relating to the same issue have been received in a short time. A substantial number of the requests have been submitted before the Agency has had an opportunity to answer earlier enquiries.

The volume and breadth of questions appears to lack focus and appears in some cases to be an attempt to obtain information without a clear idea of what might be revealed.

Many of the questions have sought information on falsified products such as Ozempic. No falsified Ozempic has been seized in the UK since Autumn 2023. The MHRA has published several press releases on the subject and much of the relevant information is already in the public domain. Earlier requests from other sources made about this area under the Freedom of Information Act are published on our website. Transparency on this subject is already high.

MHRA staff employed within the CEU are focussed on tackling the high harm and high risk threats to public safety from those engaged in medicine related crime. The abstraction from this work caused by repeated requests for information about an area where relatively small numbers are involved is distracting to staff and is adversely impacting their ability to protect public health.

Under section 16 of the FoI Act we should help you narrow your requests so that they may fall beneath the cost limit.

We feel that you should:

- Limit your requests contained in the above mentioned FoI requests.
- Consider that the information you seek is contained across multiple systems and will require a very high degree of manual processing you should look to narrow your request to specific enquiries.

We will consider afresh any revised request however we cannot guarantee that any revised request will fall within the cost limit.

If you have any queries about this letter, please contact us quoting the reference numbers 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 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

Re-use of our information

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>