Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2025/00408**

20 May 2025

Dear [redacted],

Thank you for your Freedom of Information (FoI) request received on 22 April. You wrote:

> *I write to you under the Freedom of Information Act 2000 to request information relating to the importation, seizure, and regulatory guidance for certain nootropic substances, namely:*
>
> *Piracetam*
>
> *Phenylpiracetam*
>
> *Noopept (omberacetam)*
>
> *Semax*
>
> *Pantogam active (Rac-Hopantenic acid, (D-, L- hopantenic acid))*
>
> *Pantocalcin (calcium hopantenate)*
>
> *These substances are commonly used for cognitive enhancement and/or medical purposes but have been subject to seizure in a small number of cases published online by individuals, yet there exists many cases published by other individuals reporting the import of saud nootropics without seizure of the parcel. I believe that this has been by UK Border Force and Customs officers under the Psychoactive Substances Act 2016 (PSA). As they are not listed as controlled drugs under the Misuse of Drugs Act 1971, clarity on enforcement policy and precedent is essential.*
>
> *A. Objective:*
>
> *To obtain factual data and policy documents that clarify how and why these unlicensed nootropics are classified and enforced under current UK law.*
>
> *To identify any precedents, reviews, or legal interpretations that may assist in informing future imports for legitimate, personal use.*
>
> *To gain an incentive on how it is identified that a supply of said nootropics is under 3 months of personal supply, considering that individuals may dose one ro more of the nootropic substances mentioned at highly varying doses.*

*B. Specific Information Requested*

*Please provide the following:*

*1. Seizure Data (2016-Present):*
*a. The total number of personal imports (quantities under a 3-month personal supply) seized or detained by UK Border Force or Customs for each of the listed substances.*
*b. Dates, quantities, and ports of entry (e.g., Heathrow, Dover) for each recorded seizure.*

*2. Enforcement Guidance and Policy Documents:*
*a. Any internal Home Office or Border Force guidance, Standard Operating Procedures (SOPs), or risk-assessment criteria used to determine whether these nootropics fall under the PSA.*
*b. Legal advice or ministerial correspondence concerning classification of piracetam, phenylpiracetam, noopept, semax, pantogam active and pantocalcin.*

*3. Regulatory Position and Exemptions:*
*a. Clarification on whether any of these substances are exempted when intended for medical or research use.*
*b. Correspondence with the MHRA regarding licensing status or exemption criteria for unlicensed medicines.*

*4. Determination of the Quantity of Supply Being Imported:*
*a. Any regulation used by the MHRA or the HMRC to conclude what quantity is considered to be more than 3 months of personal use, considering the fact that some individuals, for example with piracetam, report taking up to 4800 mg daily, while the starting dose for many is only 1600mg.*
*b. How the following regulation accounts for individuals which take doses lower than what is considered the effective dosage. For example, in the case of piracetam, an individual may take 400mg. This would cause a supply of piracetam which would last 1 month for a person taking 1600mg daily to be used in 4 months.*
*c. How the following regulations deal with imports of multiple substances, with one individual substance lasting less than 3 months, but their total sum would be over 3 months. For example, would a package, consisting of 4 different smaller containers, with each container including a 1 month supply of a different nootropic substance be considered a 1 month supply or a 4 month supply? Please include why this is or if such cases would be subject to different regulations*

*5. Legal Precedents and Reviews:*
*a. Copies or summaries of any tribunal decisions, court cases, or internal reviews relating to personal imports of the above substances.*
*b. Any internal Home Office analyses of appeal outcomes or recommendations to adjust enforcement policy.*

**MHRA Response**

The Agency has completed its search for the information you have requested, and we are able to confirm that we do hold some of the information and provide it below. Please note, we only hold data regarding Piracetam, as this is the only product on the list provided which has an active UK Marketing Authorisation. For clarity on enforcement policy and precedent for substances in question, please contact Border Force and HMRC.

**1. Seizure Data (2016-Present):**
**a. The total number of personal imports (quantities under a 3-month personal supply) seized or detained by UK Border Force or Customs for each of the listed substances.**

**b. Dates, quantities, and ports of entry (e.g., Heathrow, Dover) for each recorded seizure.**
We hold this information for Piracetam only and provide it below. Please contact UKBF and HMRC to get their data.

| | | |
|---|---|---|
| 01/12/2020 | 400g powder | Stansted Airport |
| 04/03/2024 | 360 tablets | Coventry Hub (mixed consignment also 360 tadalafil and 20 sildenafil) |
| 15/10/2024 | 360 tablets | Coventry Hub (mixed consignment also 360 sertraline and 180 clonidine) |
| 10/01/2025 | 40 tablets | Coquelles (mixed consignment containing total of 19,312 foreign livery medicines) |

**2. Enforcement Guidance and Policy Documents:**
**a. Any internal Home Office or Border Force guidance, Standard Operating Procedures (SOPs), or risk-assessment criteria used to determine whether these nootropics fall under the PSA.**
**b. Legal advice or ministerial correspondence concerning classification of piracetam, phenylpiracetam, noopept, semax, pantogam active and pantocalcin.**

We do not hold this information. Please contact Home Office for guidance.

**3. Regulatory Position and Exemptions:**
**a. Clarification on whether any of these substances are exempted when intended for medical or research use.**
**b. Correspondence with the MHRA regarding licensing status or exemption criteria for unlicensed medicines.**

MHRA is the regulator of medicinal products (for human use), medical devices and blood products for transfusion. If the products are captured under the definition of "medicinal product" or "medical device" set out in the Human Medicines Regulations 2012 or the Medical Devices Regulations 2002, the applicable regulatory requirements contained within these sets of regulations would apply.

**4. Determination of the Quantity of Supply Being Imported:**
**a. Any regulation used by the MHRA or the HMRC to conclude what quantity is considered to be more than 3 months of personal use, considering the fact that some individuals, for example with piracetam, report taking up to 4800 mg daily, while the starting dose for many is only 1600mg.**
**b. How the following regulation accounts for individuals which take doses lower than what is considered the effective dosage. For example, in the case of piracetam, an individual may take 400mg. This would cause a supply of piracetam which would last 1 month for a person taking 1600mg daily to be used in 4 months.**
**c. How the following regulations deal with imports of multiple substances, with one individual substance lasting less than 3 months, but their total sum would be over 3 months. For example, would a package, consisting of 4 different smaller containers, with each container including a 1-month supply of a different nootropic substance be considered a 1 month supply or a 4 month supply? Please include why this is or if such cases would be subject to different regulations**

Regulation 17 (1) of the Human Medicine Regulations 2012 provides a requirement for a person importing a medicinal product to hold a “manufacturer’s licence”. An exemption is provided at 17 (6) for a person who imports a medicinal product “for administration to himself or herself or to any other person who is a member of that person’s household”. This is often referred to as the ‘personal use’ exemption. A breach of this requirement would constitute an offence under Regulation 34(1) of the regulations.

The regulations are silent on the quantity of medicine that would meet the exemption. The MHRA is the UK Competent Authority in this area and makes decisions on a case-by-case basis.

**5. Legal Precedents and Reviews:**
**a. Copies or summaries of any tribunal decisions, court cases, or internal reviews relating to personal imports of the above substances.**

We do not hold this information. Please contact Home Office for guidance.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

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**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.

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