



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](#)

Our Ref: **FOI2026/00485**

22 May 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 1 May. You wrote:

*I am writing to make a request under the Freedom of Information Act 2000.
Please provide a list of products SKUs with a single source on the market in the UK
updated to Mar -2026 or Dec-2025. The current published list is dated 2024
For each such licence, please provide the following details in an editable Excel format:*

- * NPC Code
- * Molecule Substance (Active Ingredient)
- * NPC description (Formulation Strength Formulation Strength Unit)
- Pack size
 - * Estimated quantity packs total
 - * Estimated Packs as per PCA data
 - * NHS price per pack
 - * MAH -Authorisation Holder Company Name
 - * PL Number
 - * Legal Category (POM, P, or GSL)
 - * Current Licence Status: Using standard MHRA terminology (e.g., Active, Cancelled/Withdrawn, Expired, Lapsed, Suspended, or Under Reinstatement, under sunset).
 - * Sunset Clause Status: Please indicate if the licence is currently within its three-year Sunset Clause period or if a public health exemption has been granted.
 - *

MHRA Response

The information requested is exempt from disclosure under Section 12(1) of the Freedom of Information Act.

This is because we estimate the cost of searching for and identifying the requested information would exceed the cost limit of £600 specified in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004. 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(1) of the FOI Act, the Agency is not therefore obliged to comply with your request, and we will not be processing it further. The reason being that in order to provide you with the full information would take over 24 working hours. For example, the “Sunset Clause Status” alone would require us to open every case folder for a current granted marketing authorisation to check the Sunset Clause status. As this would run into thousands of marketing authorisation case folders that would need to be opened, Section 12(1) is engaged.

Under Section 16 of the FOI Act we should help you narrow your request so that it may fall beneath the cost limit. We advise that you restrict your request to either a smaller subset of granted marketing authorisations or ask for fewer details from your list to be provided.

Please note that we publish lists of all granted marketing authorisations on our website, please see the link below.

<https://www.gov.uk/government/collections/marketing-authorisations-lists-of-granted-licences>

Please also note that some details requested, such as “NHS price per pack”, “NPC code”, “estimated quantity packs total” and “estimated packs as per PCA data” are not held by MHRA or part of our remit as a regulator.

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

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/>