



Medicines & Healthcare products
Regulatory Agency

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

Our Ref: **FOI2026/01012**

2 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 8 September. You wrote:

Thank you for your response of 19 May 2026 (ref FOI2026/00435), and in particular for the advice under section 16 that a request restricted to Questions 1 and 2 would fall below the section 12 cost limit.

I am acting on that advice. This is a new, narrowed request. Question 3 — the pre-submission and scientific-advice counts — is withdrawn in full. That question was the sole stated cause of the cost estimate, since it would have required opening every meeting record. Nothing below requires that work.

I would also like to address the section 21 exemptions you raised, because I think the position has changed since your letter.

*Request 1 — Rx-to-OTC reclassifications, 1 January 2015 to date
I have obtained and am using the published register
(Reclassifications_Aproved_1991_-_01-3-2026.xlsx). It is genuinely useful and I am grateful it exists. For approved reclassifications I therefore withdraw the request entirely — section 21 plainly applies.*

What that register does not carry is the date the application was received alongside the grant date. I request only that single additional field for the entries already published in it, if it is held.

I am not requesting information on refused or withdrawn applications, so the section 41 and section 43 concerns in your letter fall away.

*Request 2 — one machine-readable extract of the legal-status register
This is the substance of my request, and it is one query against one table:*

PL number · product name · active substance(s) · ATC code · legal status (POM / P / GSL) · MA holder · date of first authorisation

for all currently authorised human medicines, as a single CSV or Excel file.

Your letter cited section 21 for this, pointing to the Marketing authorisations: lists of granted licences collection. Having worked with that collection, I would ask you to reconsider whether it makes this information reasonably accessible for the purpose stated:

It is published as PDF, in fortnightly instalments. It is a notice of what was granted, not an extract of the register, and it cannot be read as a dataset without re-keying thousands of entries by hand.

It runs substantially in arrears. As at 8 September 2026 the most recent instalment on the 2026 page covers 15–31 March 2026, and the page records that the 1–14 March list was added on 3 September 2026 — a lag of approximately five months.

It is incremental, not cumulative. It shows what was granted in a fortnight. It does not give the current legal status of the authorised portfolio, which is what I have asked for and what Products.MHRA.gov.uk presents one record at a time with no download.

I do not say this to be difficult. I say it because a single export of a table the Agency already maintains is, I believe, far less work for you than the alternative, and it is the only form in which the information is usable for the stated purpose.

Why this matters, briefly

I am building a consumer-healthcare intelligence platform covering the national medicines registers of Europe. Twenty-three EU member states publish exactly this data as a downloadable extract — the Netherlands, Spain, France, Belgium, Ireland and others — and it is incorporated. The United Kingdom is the significant omission, not because MHRA withholds it, but because the published form cannot be processed.

The practical consequence is that UK legal-status data in my platform currently ends in April 2026 while comparable EU markets are current to within days. I would much rather represent the UK accurately.

Format and cost

CSV or Excel preferred; any machine-readable format is welcome. I am content to receive a point-in-time snapshot rather than anything ongoing, and I make no request for commercially sensitive or unpublished information — only regulatory-decision metadata of the kind routinely published by other European national registers.

If any part of this still approaches the cost limit, I would ask that Request 2 be treated as the priority and Request 1 set aside.

I am grateful for the Agency's time, and for the section 16 advice that made this narrower request possible.

MHRA Response

Thank you for your follow-on request to FOI2026/00435. We have identified two new requests for information and have replied beneath each below.

- 1. “What that register does not carry is the date the application was received alongside the grant date. I request only that single additional field for the entries already published in it, if it is held.”**

Our response:

Please find attached an updated list of reclassifications which includes the date that the application was received (alongside the grant dates).

Please note that the time elapsed between receipt and approval of an application is not necessarily an accurate measure of MHRA assessment time. This is because the assessment clock is stopped while the MHRA is awaiting responses or additional information from applicants. The duration of these clock-stop periods varies between applications.

2. ***“one machine-readable extract of the legal-status register***

This is the substance of my request, and it is one query against one table:

PL number · product name · active substance(s) · ATC code · legal status (POM / P / GSL) · MA holder · date of first authorisation

for all currently authorised human medicines, as a single CSV or Excel file.”

Our response:

Before reaching a decision we have considered your request carefully. While we appreciate that a CSV or Excel file would be preferred, we have concerns about providing information in this manner, as unlike the file provided in response for Q.1, Q.2 requires a much larger volume of data; ‘all currently authorised human medicines’.

The lists of granted MAs that are provided online can be checked by our staff in tranches to limit inaccuracies. While we wish to be open that we have provided a full PDF previously of granted MAs for an unrelated request, we are not intending to continue with this approach. We also wish to maintain one published source of reliable information.

The ICO guidance on Section 21 outlines:

“This also means you need to direct the applicant to where they can find the information. For example, you need to indicate where in the public domain the applicant can access the information or explain what existing alternative access regime is available to them.”

[Information accessible to the applicant by other means \(section 21\) | ICO](#)

We believe this to be met by providing the links to the lists of granted MAs, and instructing you on how to alter the URL for each year (see paragraph toward the end of this letter). In terms of the criteria related to what is ‘reasonably accessible to the applicant’, this is summarised below:

“When considering if information is reasonably accessible, remember any obligations you have under other pieces of legislation, such as the Equality Act 2010 and the Welsh Language (Wales) Measure 2011.”

[Information accessible to the applicant by other means \(section 21\) | ICO](#)

We interpret your request for a CSV or Excel file to be a personal preference, rather than an obligation related to accessibility.

The ICO guidance on a preference for information to be provided in a specific format is provided below:

“You should aim to respond using the preferred means of communication if this is reasonably practical. You must decide whether it is practical to supply information in the preferred format

of the requestor. You need to take into account the costs and complexities associated with the preference and weigh these factors against your resources.”

[Request handling, Freedom of Information – Frequently Asked Questions | ICO](#)

We would require staff to check CSV or Excel rows for any errors and while this is relatively unlikely, it is nevertheless feasible that sensitive information that may have populated to a report due to a database entry error.

We currently believe that the online published PDF lists of granted marketing authorisations are sufficient for the majority of our stakeholders. Therefore, and in line with the above, we can confirm that the Agency holds this information. However, the information is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain.

However, to be helpful you can find the information you seek at [Marketing authorisations Granted in 2026 - GOV.UK](#), previous year/s can be made visible by replacing the relevant year within the URL.

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/>