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

[redacted]

Our Ref: **FOI2026/00785**

18 August 2026

Dear [redacted]

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

> *Dear Freedom of Information Officer at MHRA,*
>
> *My name is [redacted] and I am a PhD researcher at the Institute of Business Chemistry, University of Münster (Germany).*
>
> *As part of my doctoral research, I am analysing the regulatory performance of major international medicines agencies, including the MHRA, EMA, FDA, PMDA, Health Canada, Swissmedic and the Therapeutic Goods Administration (TGA). The aim of the project is to compare regulatory approval timelines using a harmonised methodology similar to the annual analyses published by the Centre for Innovation in Regulatory Science (CIRS).*
>
> *To support this research, I would like to submit the following request under the Freedom of Information Act 2000.*
>
> *Requested dataset*
> *I kindly request a machine-readable dataset (CSV or Microsoft Excel format) containing all human medicinal products classified as New Active Substances (NAS) for which the MHRA granted a Marketing Authorisation between 1 January 2021 and 31 December 2025.*
>
> *Where available, I would be grateful if the dataset could include the following variables:*
>
> *Product name*
> *Active substance (INN)*
> *Marketing Authorisation number*
> *Date the Marketing Authorisation Application was received*
> *Date the application was validated*
> *Date of Marketing Authorisation (approval date)*
> *Regulatory assessment route (e.g. National Procedure, Access Consortium, Project Orbis, Rolling Review, EC Decision Reliance Procedure (ECDRP), International Recognition Procedure (IRP), or other)*
> *Confirmation that the product is classified as a New Active Substance (NAS)*
> *The requested information will be used exclusively for non-commercial academic*

research.

The primary objective is to calculate annual regulatory approval timelines using the following methodology:

Approval Time = Marketing Authorisation Date − Validation Date

The resulting annual median approval times will be compared with those published by CIRS for other major international regulatory authorities.

If an internal dataset containing these variables already exists, I would be very grateful if it could be provided directly rather than extracting the information from individual case files.

Should any of the requested information be exempt from disclosure, I would appreciate receiving the remaining available information.

If this request is likely to exceed the statutory cost limit, I would be grateful for advice under Section 16 of the Freedom of Information Act on how the request could be refined while still enabling the calculation of annual approval timelines.

Thank you very much for your time and consideration. I appreciate your support and look forward to your response.

MHRA Response

We confirm that we hold the information you have requested.

Please find a table of the requested information attached.

Please note that the time elapsed between validation 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.

For further information about the assessment of the products, please refer to the Public Assessment Reports published on our products website:
MHRA Products | Home

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.

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