Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00304**

8 April 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 17 March. You wrote:

> *I am therefore formally refining my request in accordance with your Section 16 advice. I am entirely withdrawing all requests for manual data extraction, aggregate statistics, and correspondence searches. This refined request seeks strictly pre-existing, finalised policy documents, standard operating procedures, and the single most recent executive performance reports. Locating a current policy document or a recent Board or Executive Committee KPI dashboard does not require opening individual MAA case folders and cannot reasonably exceed the 24-hour cost limit.*
>
> *Please provide the following existing documents:*
>
> *PART I: Assessment Policies (Refined from FOI2026/00162)*
>
> *1) Clock-Stop Policies: MHRA's current written policies, Standard Operating Procedures (SOPs), or internal guidance governing the use of, and maximum permissible duration for, clock-stops during the assessment of marketing authorisation applications under the national procedure.*
>
> *2) Prolonged Clock-Stops: Any written policy or procedural document outlining the mechanism for escalating, intervening in, or expediting an MAA assessment where clock-stop periods become prolonged.*
>
> *3) CHM Meeting Guidance: MHRA's published or internal guidance regarding the typical number of CHM meetings required before a decision is reached, and the expected timeframe between a final CHM meeting and the issuance of a decision.*
>
> *4) Label Expansion Policy: MHRA's current policy or procedural guidance detailing whether an applicant may seek to expand or modify the proposed indication of a product during an active MAA assessment.*
>
> *5) ECT Guidance: The current draft or finalised version of MHRA's guidance on the acceptability of external control arms and real-world evidence in marketing authorisation applications.*
>
> *PART II: ATMP Capacity & Performance (Refined from FOI2026/00163)*

1) ATMP Resourcing: The most recent internal organogram, staffing roster, or official headcount report showing the current number of Full-Time Equivalents (FTEs) specifically qualified for or allocated to the assessment of Advanced Therapy Medicinal Products (ATMPs).

2) Current Performance Dashboard: The single most recent monthly or quarterly KPI dashboard, performance report, or equivalent summary document presented to the MHRA Board or Executive Committee detailing current MAA assessment timelines and backlogs.

3) ATMP Capacity Assessment: The most recent Board or Executive Committee paper or formal internal report produced since January 2025 specifically addressing MHRA's capacity to assess ATMP applications within statutory timeframes.

If MHRA attempts to apply Section 12 to this narrowed request for specific, pre-existing corporate documents, I will immediately escalate the matter to the Information Commissioner's Office as a failure to comply with Section 1.

MHRA Response

We confirm that we hold some of the information you have requested, we have repeated your questions below and provided our responses beneath each numbered entry.

1) "Clock-Stop Policies: MHRA's current written policies, Standard Operating Procedures (SOPs), or internal guidance governing the use of, and maximum permissible duration for, clock-stops during the assessment of marketing authorisation applications under the national procedure."

Our Reply:
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. Please refer to Schedule 11, paragraph 3.

The Human Medicines Regulations 2012

Advice and assistance
Information published within the links below may also be of interest to you.
National assessment procedure for medicines - GOV.UK
Submission and assessment timetables for innovative medicines applications - GOV.UK

2) "Prolonged Clock-Stops: Any written policy or procedural document outlining the mechanism for escalating, intervening in, or expediting an MAA assessment where clock-stop periods become prolonged."

Our reply:
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.

The Human Medicines Regulations 2012

please refer to the text under the title of ‘Exceptions to requirement to consult’ at the above weblink.

What the information means in practice
The regulatory clock is stopped when additional information is requested from the applicant. Clock stop durations are outside of MHRA control; the exception being if an applicant fails to submit the information requested within 6 months from the date of request, whereby the MHRA can give notice of intention to refuse the application.

3) “CHM Meeting Guidance: MHRA's published or internal guidance regarding the typical number of CHM meetings required before a decision is reached, and the expected timeframe between a final CHM meeting and the issuance of a decision”.

Our reply:
We can confirm that the Agency holds this information. However, some of 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. Please refer to Schedule 11 of the Human Medicines Regulations 2012 which details the scenarios where the licensing authority needs to consult with CHM.

The Human Medicines Regulations 2012
Submission and assessment timetables for innovative medicines applications - GOV.UK

Further, the published guidance on the National assessment procedure for medicines (National assessment procedure for medicines - GOV.UK) outlines when an application will be presented to expert advisory committees, including the Commission on Human Medicines (CHM).

In line with the legislation, if the licensing authority is minded to refuse an application it must consult with independent expert advisory committees. Should the expert committees agree with the assessment, a letter will be issued from the CHM that outlines the deficiency points and the reason that the grant of a marketing authorisation cannot be recommended.

If the applicant wishes to make representations to the CHM, they can do so within a defined period of time. If representations are submitted, the final CHM recommendation on an application will be made on consideration of the evidence presented as part of a written representation (usually in 1 CHM meeting) or an oral hearing (usually in two CHM meetings - one meeting for consideration of the written responses and second meeting to consider the oral representations).

The decision is communicated to applicant by the MHRA as soon as is reasonably practicable after the CHM meeting; typically occurring within 7 days. We have also provided a copy of the guidance which is sent to applicants; please refer to attached file named “COMMISSION ON HUMAN MEDICINES GUIDANCE NOTE FOR APPLICANTS REPRESENTATIONS 2026 v1.0”.

4) “Label Expansion Policy: MHRA's current policy or procedural guidance detailing whether an applicant may seek to expand or modify the proposed indication of a product during an active MAA assessment”.

Our reply:
We hold no information explicitly related to the scenario mentioned in your request.

Advice and assistance
The MHRA regulates medicines, including vaccines, supplied in the UK. Our activity spans the whole of a medicine's lifecycle. We decide whether medicines should be granted licences (also known as Marketing Authorisations) and whether licences can be varied as information about the medicines develop. These decisions are based on safety, quality and effectiveness data submitted to us.

Based on our current practice, it is possible for the proposed indication to be modified or expanded during an active MAA assessment as long as any change is supported by the submitted clinical data/emerging safety data.

If additional clinical data on efficacy that was not agreed during the start of the procedure or submitted in response to a question, become available to support an expansion of the indication in the latter stages of the procedure, expansion of the indication would be considered as a post-approval variation.

5) ECT Guidance: The current draft or finalised version of MHRA's guidance on the acceptability of external control arms and real-world evidence in marketing authorisation applications.

Our reply:
We can confirm that the Agency holds this information. However, some of 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. Please refer to the link below.

Draft_MHRA_Guideline_on_Studies_with_RWD_ECA_May2025.pdf

Advice and assistance
To provide background context and details related to the draft guideline, we are also providing the link below.

MHRA draft guideline on the use of external control arms based on real-world data to support regula…

PART II: ATMP Capacity & Performance (Refined from FOI2026/00163)

1) ATMP Resourcing: The most recent internal organogram, staffing roster, or official headcount report showing the current number of Full-Time Equivalents (FTEs) specifically qualified for or allocated to the assessment of Advanced Therapy Medicinal Products (ATMPs).

Our reply:
We can confirm that the MHRA does not hold this information. The Agency does not have dedicated resources assigned to a specific ATMP team; therefore, there is no organogram or staffing data available to provide.

For context, the MHRA convenes individuals on a case-by-case basis, drawing on relevant expertise from across the Agency. These individuals are part of different teams and bring a range of specialised disciplines. As a result, any attempt to provide staffing figures or an organogram would be misleading and would not accurately reflect how this work is delivered.

2) Current Performance Dashboard: The single most recent monthly or quarterly KPI dashboard, performance report, or equivalent summary document presented to the MHRA Board or Executive Committee detailing current MAA assessment timelines and backlogs.

Our reply:
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 the below weblink.
MHRA Performance Data - GOV.UK

Advice and assistance
The subsection you may be most interested in is under the title 'Medicines licence applications via the national route' where median assessment times are listed.

3) ATMP Capacity Assessment: The most recent Board or Executive Committee paper or formal internal report produced since January 2025 specifically addressing MHRA's capacity to assess ATMP applications within statutory timeframes.

Our reply:
We hold no information related to this request. We have searched our records and used search terms 'ATMP' and 'Advanced' to search the board papers and executive committee papers since January 2025 onwards. No information was identified relating to ATMP or Advanced Therapy Medicinal Products in relation to capacity to assess or related to resourcing dedicated to these types of products.

Advice and assistance
In future, you may wish to visit the below link to check back to see if resourcing / capacity topics are discussed. However, we only publish the minutes of the boards held in public online and there are two of these per year.

Our governance - Medicines and Healthcare products Regulatory Agency - GOV.UK

Broad advice and assistance
We have noticed that your previous FOI requests related to DC-Vax-L, while we cannot divulge further information about a marketing authorisation application (MAA). We wish to reiterate some points from the internal review response issued in February.

"However, please be assured that MHRA assesses new marketing authorisation applications for medicinal products as quickly as possible. We have very strict timelines for when we have to come to a decision on whether to grant a marketing authorisation for a product or not. However, these timelines do not include time when we are waiting for further information from the applicant themselves. Time waiting for further information from applicants can be lengthy in instances where the applicant is required to do additional research to answer the points raised by MHRA assessors. These points are raised to ensure that the product is safe and the benefit/risk balance favours granting a marketing authorisation. We suggest that, as Northwest Biotherapeutics have already put information into the public domain, you contact them for further information on their products."

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