to ask for a ‘timeline’ of key dates? I wondered if this would be useful information. If so, please let us know and we can log a new request for you."

On a separate note, it would be useful for me to see evidence of how learnings have been taken from the situation to better inform patients and parents on updates. We had no communication in 4 years. I'm guessing this is more.for the complaints depart

Thanks

[redacted]

Sent from Outlook for Android

From: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Sent: Thursday, February 29, 2024 4:35:55 PM
To: [redacted]
Subject: FOI 24/139 - Status up on MAGEC Rods MDA/2020/010

FOI 24/139

Dear [redacted]

Thank you for speaking to me earlier today; as I mentioned, I didn’t want you just to receive a lengthy and formal refusal of your FOI request, so I’m ever so grateful for the chance to talk through FOI a little with you.

As I explained, there is a ‘formal’ section below, but I will then move to some advice and suggestions about how you might be able to make a request for a smaller amount of information which would still be useful for you.

This is your request:

> **RE:** Status up on MAGEC Rods MDA/2020/010 - the additional requirements the manufacturer needs to meet
>
> **With reference to the above, under the Freedom of Information Act, please provide the following information within 20 days working days as stated by law:**
>
> - Complete reports on what these additional requirements are that the manufacturer needs to meet
> - Communication - I want to see emails and minutes of the meetings where these requirements have been discussed - including dates and times.
> - A roadmap of how these requirements will be met

First of all, as mentioned earlier, I’m sorry that we do need to refuse your request; this is because, in covering the whole 4 year period, there is a very large amount of information which we would need to retrieve from case files and folders. The FOI Act has what’s called an ‘appropriate limit’ of 24 working hours allowed for us to locate, retrieve and extract (from other documents and files) the information relevant to the request; if it would take over 24 for this part of the request handling process, then we can apply section 12(1) of the FOI Act and refuse the information.

For your request, the main time needed would be to review files to identify all the reports that might meet the first part of your request, and to locate and retrieve all the emails that have been exchanged over the time period. This part is particularly time-consuming as over time, certain colleagues have left the MHRA, and to make sure we have found all the relevant information that we might hold, we would need to ask for our IT department to conduct searches of the colleagues’ mailboxes – these are quite broad searches, and even using

filtering and keywords they can produce many duplicated results, and some that aren't relevant, so we then need to manually go through all the results to extract the relevant ones.

I hope that this explains why we need to apply section 12(1) for your request. However, I also mentioned the importance of providing further advice and assistance to you, so we can help you to make a smaller request.

A way to do this might be to focus on, if not the dates and times of each email (as I'd still be a bit concerned about how long it would take to retrieve and review the older emails in an IT search), then to ask for a 'timeline' of key dates? I wondered if this would be useful information. If so, please let us know and we can log a new request for you.

I should say, once we are able to retrieve information for you, we move to the 'decision-making' stage of request handling, to determine whether the information can be disclosed or if an exemption applies. As part of this, once we have a set of information, we will still need to ask the company for their views on the disclosure, and I mentioned to you that usually in these situations companies are very cautious about disclosing any information that they believe would be useful to their competitors or could prejudice them. I can't know in advance what the decision would be on any particular information, but my general advice about this would be to focus on higher level information rather than specific reports (which will contain discussion of technical information about a product).

I am sorry again that we can't provide all the information you asked for this time, but I do hope that this explanation and my suggestions will still be helpful for you.

With best wishes,

[redacted]

Freedom of Information Manager
MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

Appeal rights

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering or handling your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to:
Information Commissioner's Office,
Wycliffe House,
Water Lane,

Wilmslow,
Cheshire,
SK9 5AF

Yours sincerely,

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

From: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Sent: Monday, February 12, 2024 12:21 PM
To: [redacted]
Subject: FOI 24/139 Status up on MAGEC Rods MDA/2020/010: Concerned Parents - Urgent response from a PIC

Dear [redacted]

I am the FOI Manager at the MHRA and I am writing to you in response to your emails of 8 February 2024 and 1 February 2024.

First of all, I would like to confirm that we have received the FOI request that you included in your email to MHRA Customer Services on 8 February 2024, and I would like to apologise for our delay in acknowledging this. I've copied the wording of your request here:

> **RE:** Status up on MAGEC Rods MDA/2020/010 - the additional requirements the manufacturer needs to meet
>
> **With reference to the above, under the Freedom of Information Act, please provide the following information within 20 days working days as stated by law:**
> - Complete reports on what these additional requirements are that the manufacturer needs to meet
> - Communication - I want to see emails and minutes of the meetings where these requirements have been discussed - including dates and times.
> - A roadmap of how these requirements will be met

To explain what will happen next, we will now allocate your request to the team who manage the area of the MHRA's work that you have asked about; they will then identify the information you have requested and work through the information against the provisions of the FOI Act to determine whether the information may be disclosed or if an exemption applies. I am an expert in the application of the FOI legislation, and my role is to provide advice to the team throughout the handling of your request as required.

I understand that you have also explained that you are unhappy with the handling of your previous correspondence to the MHRA, particularly in regard to the three points you have set out in your email of 8 February 2024. These particular points do not fall under the FOI legislation, but I can advise that these will be addressed as an administrative complaint. My colleagues in the Customer Services team will contact you in a separate email to give you a timeframe and reference number for this complaint.

However, I have reviewed your previous correspondence, and I can see that your email of 1 February 2024 also asked for information about the requirements and clearly expressed that you were disappointed with the reply that the MHRA had