

**FOI 23/815**

Dear

Thank you for your request for information dated 25 October 2023, where you asked.

*“I am seeking clarification regarding the determination times for line extensions. According to the metrics data [PowerPoint Presentation \(publishing.service.gov.uk\)](#) (MHRA performance, Assessment of New Marketing Authorisation Applications and Variations January – September 2023), data for line extensions is included within the initial established medicine graphs (Figure 10). However, I am interested in understanding whether the current timelines, particularly the 800-day period for nationals, also apply to line extensions. I am keen to know if there are variations in the processing times for line extensions compared to other established medicines.*

*If possible, I kindly request that you provide any relevant documents, guidelines, or data related to the determination times for line extensions within the MHRA’s regulatory framework.*

*Please feel free to contact me via email should any aspect of my request require further clarification. I appreciate your attention to this matter and thank you in advance for your timely response.”*

**Our response:**

Please find below a table related to numbers of line extensions granted in the requested period and the duration from validation to determination of the applications. Please note these are total numbers of licences granted and include multiple strengths of the same product. These figures have been generated from information held in our database.

		Number of applications for line extensions granted	Median number of days from validate case to determination (total elapsed days since validation)
Jan 2023	National	1	593
	Reliance	1	70
Feb 2023	National	3	567
	Reliance	2	49
March 2023	National	1	270
	Reliance	1	35
April 2023	National	1	459
	Reliance	5	89
May 2023	National	0	-
	Reliance	1	155
June 2023	National	0	-
	Reliance	4	114
July 2023	National	3	1595
	Reliance	1	155
Aug 2023	National	4	823
	Reliance	12	160
Sept 2023	National	7	143
	Reliance	9	110

We trust that you will find this information of use, but if you have any further questions please do let us know.

## **Your right to seek a review**

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

### **HQA FOI Team**

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