Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

4 April 2024

Dear [redacted],

Internal review of FOI 24/156

I am writing in response to your request of 7 March 2024 for an internal review of the Medicines and Healthcare products Regulatory Agency's ('the Agency') response to your FOI request (**FOI 24/156**).

I confirm that an internal review has been conducted and hereby set out its findings.

Request history

On 14 February 2024, you made the following request for information:

> "I understand that the drug Keytruda has been approved for use in the paediatric population in the UK. I therefore assume that the marketing authorisation holder has received from MHRA a notice of compliance with an agreed paediatric investigation plan (PIP).
>
> I would like to request a copy of this document. Please can you provide it?
>
> I note that the corresponding document from the EMA is publicly available – see attached."

On 06 March 2024 we responded with the below:

> "Regarding your request for information on the agreed paediatric investigation plan (PIP) for KEYTRUDA 25 mg/mL concentrate for solution for infusion (PLGB 53095/0040), this product was authorised following a centralised procedure on 17 July 2015. As the UK was still an EU member state at the time of authorisation and

also when the EMA released the attached statement of compliance (dated 27 June 2019), no statement would have been provided separately by MHRA, as we would have complied with the attached EMA statement. Therefore, we hold no additional documents to the published EMA document you have referred to in your original request."

On 7 March 2024 you requested an internal review.

> "I am aware that the usual policy of the MHRA would be to rely upon a compliance statement issued by the EMA under circumstances such as KEYTRUDA. However, I have direct evidence that MHRA has nonetheless issued a compliance statement for KEYTRUDA at the request of the marketing authorisation holder, Merck.
>
> Please see attached a letter filed by Merck at the UK Intellectual Property Office (UKIPO) and visible in the UKIPO public record. This letter explicitly refers to the said compliance statement, which was provided to the UKIPO as an attachment. The compliance statement was evidently issued at some stage between July and November 2023.
>
> The UKIPO public file includes the letter, but not the attached compliance statement. The UKIPO would not share the compliance statement with me on the basis that this document is between Merck and the MHRA. The UKIPO believe they are not free to share it because MHRA is another UK government department.
>
> Hence, my request under FOI is that you (the MHRA) release the compliance statement to me directly.
>
> Please can you check your records again in light of the above. I believe you will find that you do (or at least should) hold a compliance statement for KEYTRUDA, dated between July and November 2023."

1. Issues on review

The internal review considered.

I) whether your request was handled appropriately under the FOIA.

2. Conclusion and recommendations

For this review, we have conducted further searches and we have located the relevant information. We apologise that this was not located in our initial handling of the request.

The MHRA compliance statement was requested by MSD in November 2023 via a type IB procedure as the MHRA copy to the EMA Compliance Statement document. The statement which we have attached alongside this letter was issued to the company on 6 November 2023.

I hope that this review is useful for you and has clarified the position on the information you requested. If you remain dissatisfied, you may ask the Information Commissioner (ICO) to make a decision on whether or not we have interpreted the FOIA correctly in dealing with the request and subsequent internal review. The ICO's address is below.

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Yours sincerely,

HQA FOI Team