



Medicines & Healthcare products  
Regulatory Agency

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United Kingdom  
[gov.uk/mhra](https://www.gov.uk/mhra)

[REDACTED]

[REDACTED]

10 May 2024

MHRA reference: FOI2024/00040

Dear [REDACTED],

Thank you for your information request, which we received on 19 April 2024. You asked for:

*I would like to find out just what the MHRA are doing with regard to the consideration and approval of the drug Sipavibart and the time span and process involved before regulatory approval is granted. Please provide all meeting notes advice to DHSC, ministers etc concerning this drug and its benefits to the immunosuppressed/compromised.*

*Has the use of Human Medicine Regulations 2012 Section 174 been considered or being considered if not why not?*

*Lessons can be learnt from eg the FDA which have already given Emergency Use Authority as they have in France and I believe Finland.*

*Please answer the above request as fully as possible, as I can assure you it's very much in the interest of the parties that are awaiting the drugs approval to be fully informed of what is going on.*

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

We can confirm that no product containing the active ingredient sipavibart has been authorised by MHRA.



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Unfortunately, we cannot provide information on whether there may or may not be an application in progress for any particular product. When we need to refuse a written request for information in this way, we need to do this under the provisions of the Freedom of Information Act 2000 (FOIA) so that we include the relevant exemptions and the reasons why we are applying them. This means that for your enquiry about sipavibart we need to refuse to confirm or deny whether we hold this information under Section 41(2) (S41 – information provided in confidence) and Section 43(3) (S43 – prejudice to commercial interests) of the FOIA.

We will explain these exemptions below.

### **Section 41 –**

(2) The duty to confirm or deny does not arise if, or to the extent that, the confirmation or denial that would have to be given to comply with section 1(1)(a) would (apart from this Act) constitute an actionable breach of confidence.

### **Section 43 –**

(1) Information is exempt information if it constitutes a trade secret.

(2) Information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).

(3) The duty to confirm or deny does not arise if, or to the extent that, compliance with section 1(1)(a) would, or would be likely to, prejudice the interests mentioned in subsection (2).

### **Public interest test**

Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when considering the neither confirm nor deny provision of a qualified exemption. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in neither confirming nor denying that the information is held outweighs the public interest in confirming or denying whether the MHRA holds the information you have requested. The ‘public interest’ is not the same as what interests the public. In carrying out a PIT, we consider the greater good or benefit to the community as a whole in saying whether information is held or not. The ‘right to know’ must be balanced against the need to enable effective procedural governance and to serve the best interests of the public. The FOI Act is ‘applicant blind’. This means that we cannot, and do not, ask about the motives of anyone who asks for information. In providing a response to one person, we are expressing a willingness to provide the same response to anyone.

### **Considerations in favour of confirming whether or not we hold the information**

To confirm or deny whether or not an application has been received by MHRA would be of interest to patient groups and healthcare professionals in knowing and understanding whether a relevant treatment could soon be available to patients. It would also be of benefit in general to show transparency in MHRA’s day-to-day work for the public to see what applications are currently being considered by MHRA.



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### **Considerations in favour of neither confirming nor denying whether we hold the information**

To confirm or deny whether we are currently considering an application for a particular medicine would be of great interest to rival companies who are marketing or looking to market their own products. Knowledge of whether an application is being considered by MHRA can be used as market intelligence in order to gauge when a new product is likely to come onto the market so strategies can be employed to prevent that product getting a foothold in the market. Further, to confirm or deny that we may hold any information on applications that are not yet authorised in the UK can create a chilling effect, with companies reluctant or unwilling to submit applications for their products to the UK. This would result in fewer medicines being available for patients.

This concludes our response to your request.

If you have a query about this response, please contact us at [foi.request@mhra.gov.uk](mailto:foi.request@mhra.gov.uk)

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Health Quality and Access Division  
**Medicines and Healthcare products Regulatory Agency**

### **Appeal rights**

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: [foi.request@mhra.gov.uk](mailto:foi.request@mhra.gov.uk)

If you remain dissatisfied with the outcome of the internal review, you 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 a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: <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