FOI 24/114 New drug Marketing Applications

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Thu 22/02/2024 14:48
To [redacted]

FOI 24/114

Dear [redacted]

Many thanks for your request of 1 February 2024 where you asked “I would like to know when the applications for SYFOVRE® (pegcetacoplan injection) and the application for IZERVAY (avacincaptad pegol intravitreal solution) were submitted.”

No products called SYFOVRE or IZERVAY have been authorised by MHRA. Regarding whether an application for either product has been received by MHRA, we neither confirm nor deny we hold information relevant to your request. Section 41(2) and Section 43(3) of the Freedom of Information Act (FOIA) absolves us from the requirement to say whether or not we hold information:

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.

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.

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.

You may want to contact the companies concerned to ask them about whether they have submitted applications to MHRA for either product.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied 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 at:

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: [redacted]
Sent: Thursday, February 1, 2024 9:37 AM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 24/114 New drug Marketing Applications

You don't often get email from [redacted] Learn why this is important

Hi

I am hoping you can help me.

I am wondering how to check the UK medical and Health Care production Regulatory Agency (MHRA) database for drugs applications https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

In particular I would like to know when the applications for **SYFOVRE®** (pegcetacoplan injection) and the application for **IZERVAY** (avacincaptad pegol intravitreal solution) were submitted. Syfovre was approved by the FDA march 2023 but rejected by the EMA in January 2024. The company Apellis are going to appeal. Izervay was approved by the FDA in August 2023 and the company Iveric Bio made their application to the EMA in August 2023 so it could be August 2024 before there is a result.

The background to this is that my partner suffers from Geographic Antrophy and is travelling to the US every two months for this treatment. We were expecting a time lag of approx. 2.5 years before the drug was available in Europe/UK. We were disappointed when the EMA rejected the application for Syfovre in January but not overly surprised as the EMA have more stringent guidelines than the FDA. I would really like to know the current UK position on both of these drugs and to be able to check the UK database for updates intermittently.

Any help you can give me would be greatly appreciated.

Regards

[redacted]

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