Medicines & Healthcare products Regulatory Agency

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

[redacted]

8 November 2023

FOI 23/773

Dear [redacted]

[redacted] approval for Enhertu in the treatment of Non-Small Cell Lung Cancer (NSCLC).

We have identified that this request would come under the Freedom of Information Act and have treated it under the FOI Act.

Enhertu (trastuzumab deruxtecan) 100 mg powder for concentrate for solution for infusion (PLGB 08265/0046) is currently authorised for the following indications:
Breast cancer

HER2-positive breast cancer
Enhertu as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic HER2 positive breast cancer who have received one or more prior anti HER2 based regimens.

HER2-low breast cancer
Enhertu as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic HER2-low breast cancer who have received prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy (see section 4.2).

Gastric cancer

Enhertu as monotherapy is indicated for the treatment of adult patients with advanced HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen.

Enhertu (trastuzumab deruxtecan) 100 mg powder for concentrate for solution for infusion (PLGB 08265/0046) is not currently authorised for use in NSCLC. Whether MHRA has

received an application for the use of this medicinal product in NSCLC, we refuse to confirm or deny we hold any information under Section 41 (S41) and Section 43 (S43) of the Freedom of Information Act (FOIA). S41 is an absolute exemption, and no consideration of the public interest is required, except to state that we would consider the release of this information to be an actionable breach of confidence. S43 is a conditional exemption and requires a consideration of the public interest. We have considered the public interest and cannot see any public interest argument that outweighs the commercial harm in alerting competitors to whether a company is close to obtaining authorisation for the use of a medicinal product for a particular indication.

Please be aware we publish FOI replies and these are redacted at the following link of our website below and if you wish to consult with companies or the customer for redactions then please do and let us know.
https://www.gov.uk/government/collections/freedom-of-information-responses-from-the-mhra-2021

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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 online via an electronic form:
https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or

by writing to:

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

We apologise for the delay in this reply, but we hope this information is helpful.

Yours sincerely

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