

FOI 23/172 - Enhertu approval

Request

02 March 2023

Would you kindly advise when Enhertu medicine will be approved in the UK?

MHRA response

26 March 2023

Thank you for your email.

Enhertu Infusion 100 mg (PLGB 08265/0046) was granted on 12 February 2021. It is authorised:

- 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.
- 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.

Concerning the deployment of this authorised product in the NHS, we advise that you contact NICE or NHS England for further information.

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 at:

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

Yours sincerely

MHRA Customer Service Centre

Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU