Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

22 March 2024

Dear [redacted]

FOI 24/188

Thank you of your email, dated 24 February 2024, in which you requested:

"1. A copy of the latest version of the Risk Management Plan for Trastuzumab deruxtecan (Enhertu), including Annexes
2. A copy of Enhertu´s "ILD Assessment Summary" (as referenced on page 47 of RMP Version 1.0: https://assets.publishing.service.gov.uk/media/628e16c0e90e071f63e25672/FOI_21-1273-1.pdf)
3. Copies of the Final Reports for the 2 studies listed in Enhertu´s Post-Authorisation Development Plan (as per Table Part III.3.1 on page 54 of RMP Version 1.0: https://assets.publishing.service.gov.uk/media/628e16c0e90e071f63e25672/FOI_21-1273-1.pdf):
   a) "EU survey of relevant healthcare professionals on understanding of key risk minimization measures pertaining to ILD/pneumonitis" (final report due date: Q3/2023)
   b) "Collection and analysis of PK and safety data in subjects with moderate hepatic impairment from ongoing clinical studies" (final report due date: Q4/2023)"

We can confirm that the MHRA holds a copy of the requested RMP, the ILD Assessment Summary and copies of the final reports for the 2 studies listed in Enhertu´s Post-Authorisation Development Plan. Please find these documents attached to the email.

Information that has been redacted is exempt under Section 40 (Personal Information) or Section 43 (Commercial Interests) of the Freedom of Information (FOI) Act and is therefore withheld.

Section 40 provides that personal information may be exempt from release where to do so would contravene data protection principles. Section 43 provides that information will be exempt from release where to do so would or would be likely to prejudice commercial interests. Furthermore, we do not believe that there is an overriding public interest in disclosing the redacted information in this instance.

We hope the information provided is helpful, but 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 of this response; and can be addressed to this email address.

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

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

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