FOI 24/219 RE: Pemetrexed 10 mg/ml solution for infusion-PAR request

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Fri 15/03/2024 15:04
To [redacted]
Our ref: FOI 24/219

[redacted]

Regarding your request for the Public Assessment Reports (PARs) for Pemetrexed 10 mg/ml solution for infusion (PL 17780/1156) and Pemetrexed 10 mg/ml solution for infusion (PL 31750/0193), please see our response below.

Pemetrexed 10 mg/ml solution for infusion (PL 17780/1156) was authorised on 13 May 2022 following a reliance procedure in the UK that was based on a previous decentralised procedure in the European Union (EU), with Germany as the Reference Member State (RMS; DE/H/6705/001/DC). The links to the PARs published by MHRA and by the German regulator are provided below:
https://mri.cts-mrp.eu/portal/details?productnumber=DE/H/6705/001
https://mhraproducts4853.blob.core.windows.net/docs/7b802aedce788644e07afa0d7b16bc1e83fa02cf

Pemetrexed 10 mg/ml solution for infusion (PL 31750/0193) was authorised on 13 December 2021 following an incoming decentralised procedure with the Netherlands as RMS (NL/H/5223/009/DC). As the UK was a Concerned Member State for this European procedure, no PAR was published by MHRA. A link to the PAR published by the Netherlands regulator is provided below:
https://mri.cts-mrp.eu/portal/details?productnumber=NL/H/5223/009

If you have a query about the information provided, please reply to this email

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

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

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: Wednesday, February 28, 2024 3:42 PM
To: FOI_Policy <FOI_Policy@mhra.gov.uk>; MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: RE: Pemetrexed 10 mg/ml solution for infusion-PAR request
Importance: High

Dear Sir/Mam,

I'm writing you to request the Public Assessment Report for below product(s);

Product 1
Product Name: Pemetrexed 10 mg/ml solution for infusion
MA No: PL 17780/1156
MAH: Zentiva Pharma UK Limited
Date of authorization: 13/05/2022

Product 2
Product Name: Pemetrexed 10 mg/ml solution for infusion
MA No: PL 31750/0193
MAH: Sun Pharmaceutical Industries Europe B.V.
Date of authorization: 13/12/2021

The PAR for above mentioned product(s) are not available on the MHRA's website. Could you please provide the same.

Your prompt response would me much appreciated.

Thanking you in advance.

[redacted]

[redacted]

[redacted]

Pharmaceuticals Limited immediately by telephone and/or send an email to [redacted]