FOI 24/157 - RE: Request for Public Assessment Reports (PAR)

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Tue 05/03/2024 14:55

To: [redacted]

FOI 24/157

Dear [redacted]

Regarding your request for the Public Assessment Reports (PARs) for specific products, please see our response below. As this information is available to you on either the MHRA or the European Medicines Agency's (EMA's) website, Section 21 of the FOIA applies and we are providing links to each PAR in our response below.

For any future requests for PARs, please check the EMA website or the MHRA Product Portal for the PAR (see below links), and please note that MHRA does not publish PARs for Centralised products authorised before we left the European Union.

https://www.ema.europa.eu/en/medicines

https://products.mhra.gov.uk/

1) Etranacogene dezaparvovec (Hemgenix®)

A PAR for this product has been published, please see the link below:

https://mhraproducts4853.blob.core.windows.net/docs/8dcbd83799317a10cfe5a2551123b649e6541609

2) Valoctocogene roxaparvovec (Roctavian®)

There is no authorised product called "Roctavian" and no active substance authorised called "valoctocogene roxaparvovec."

3) Exagamglogene autotemcel (Casgevy®)

A PAR for this product has been published, please see the link below:

https://mhraproducts4853.blob.core.windows.net/docs/6207c5b52c87d702cc0e599ddf9846f5d0d0c860

4) Tisagenlecleucel (Kymriah®)

Kymriah was authorised by the EC on 23 August 2018 (EMEA/H/C/004090). As this predates the UK leaving the EU, no assessment was made by the UK as a sovereign regulator and so no PAR was published by MHRA for this product. A PAR has been published by the EMA, linked below:

https://www.ema.europa.eu/en/medicines/human/EPAR/kymriah

5) Axicabtagene ciloleucel (Yescarta®)

Yescarta was authorised by the EC on 23 August 2018 (EMEA/H/C/004480). As this predates the UK leaving the EU, no assessment was made by the UK as a sovereign regulator and so no PAR was published by MHRA for this product. A PAR has been published by the EMA, linked below:

https://www.ema.europa.eu/en/medicines/human/EPAR/yescarta

6) Betibeglogene autotemcel (Zynteglo®)

Zynteglo was authorised by the EC on 29 May 2019 (EMEA/H/C/003691). As this predates the UK leaving the EU, no assessment was made by the UK as a sovereign regulator and so no PAR was published by MHRA for this product. A PAR has been published by the EMA, linked below:

https://www.ema.europa.eu/en/medicines/human/EPAR/zynteglo

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: Tuesday, February 6, 2024 1:21 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: Request for Public Assessment Reports (PAR)

You don't often get email from [redacted]

Hello there,

I hope you are having a great weekend. I have used your website to check out a few products – and I am wondering if you will have any Public Assessment Reports (PAR) available for the products / active substances listed below as they are not on the website?

1. Etranacogene dezaparvovec (Hemgenix®)
2. Valoctocogene roxaparvovec (Roctavian®)
3. Exagamglogene autotemcel (Casgevy®)
4. Tisagenlecleucel (Kymriah®)
5. Axicabtagene ciloleucel (Yescarta®)
6. Betibeglogene autotemcel (Zynteglo®)

Please let me know if you have any of the PAR for the active substances listed and if you can provide any of them.