FOI 24/067- Query-PAR info MHRA-PLGB licenses

FOILicensing <FOILicensing@mhra.gov.uk>
Wed 07/02/2024 09:44
To [redacted]

FOI 24/067

Dear [redacted]

Thank you for your email dated 15 January 2024, where you requested if the PAR for Tenkasi(Oritavancin) PLGB 16239/0060 is available or not.

Please find our response to your request below:

The Marketing Authorisation for Tenkasi(Oritavancin) PLGB 16239/0060 was converted from an EC Centralised authorised product (CAP) to a GB marketing authorisation on 01 January 2021, following our departure from the EU. We do not routinely publish UKPARs for such products.

Please refer to the EMA public assessment report which can be found using the following link Tenkasi (previously Orbactiv) | European Medicines Agency (europa.eu).

We now consider this response closed. If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review. Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content 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 in writing to:

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

Yours sincerely,
HQA FOI Team

From: [redacted]
Sent: Monday, January 15, 2024 12:37 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 24/067- Query-PAR info MHRA-PLGB licenses

Dear Service team,

Thank you so much for the information.

I am looking for Tenkasi(Oritavancin) - PLGB 16239/0060 PAR.Could you please advise whether it is available or not

Thanks

[redacted]

On Mon, 15 Jan 2024 at 10:52, MHRA Customer Services <MHRACustomerServices@mhra.gov.uk> wrote:

> Dear [redacted],
>
> I hope all is well. Apologies about the delay in responding. Thank you for your patience.
>
> We have not routinely published Public Assessment Reports (PARs) for marketing authorisations that were converted from EC Centralised authorised products (CAPs) to UK marketing authorisations on 01 January 2021, following our departure from the EU. These products will have an EPAR published on the European Medicines Agency (EMA) website.

When there is a national Type II variation for such a CAP conversion product, where MHRA conducted a full assessment, we have subsequently published a PAR.
We routinely publish PARs for marketing authorisations granted via the EC reliance route (i.e. marketing authorisations that have been granted relying on a decision taken by the European Commission) and these will be available on our website:
MHRA Products | Home
If you are looking for a PAR for a particular product, please let us know and we will be able to advise whether a PAR is available, and any reason for it not currently being available.
Best Wishes,

[redacted]
MHRA Customer Experience Centre
Communications and engagement
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
Telephone 020 3080 6000
gov.uk/mhra
Stay connected

From: [redacted]
Sent: Thursday, January 4, 2024 7:04 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Cc: [redacted]
Subject: [redacted]

You don't often get email from [redacted]

Dear Sir/Madam,
This query is regarding PAR(Public assessment report) details of licenses converted to PLGB licenses.
While checking in MHRA products I cannot find PAR for the PLGB license. Could you please advise what is the reason for it? Is there any guidance on the PAR for GB.
Thanks in advance
[redacted]
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[redacted]

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