FOI 24/206 RE: BMJ enquiry Slynd (drospirenone progestogen-only contraceptive) PL 44081/0005

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

Fri 01/03/2024 13:32

To [redacted]

FOI 24/206

Dear [redacted]

Thank you for your request for information dated 17 January 2024. We apologise for the delay in getting back to you. For ease I have numbered your questions and provided responses beneath.

1. Please can you send me a copy of the UK public assessment report for Slynd (drospirenone progestogen-only contraceptive) PL 44081/0005.

Our response
Information not held.

Advice and assistance
The reference member state for the decentralised procedure (DCP) was Sweden. Therefore, the Swedish competent authority would be responsible for creation of the PAR. I advise contacting the Swedish Authority to ask if they have a PAR available: Contact us | Swedish Medical Products Agency (lakemedelsverket.se). The reference number to include in any further correspondence with the Swedish regulator is SE/H/1893/001/DC (DCP).

2. Was the UK market authorisation approval based on the assessment report conducted by the Swedish Medical Products Agency?

Our response
We hold information relevant to this request as follows. We can confirm that the application for this product was approved initially in SE in 2019 by decentralised procedure (DCP) outcome dated 26.09.2019. Prior to that this application was seen by the UK, as CMS, in a DCP with DE as RMS in 2016.

The currently granted MA in the UK was a repeat-use procedure of the above mentioned Sweden led DCP SE/H/1893/001/DC, so to confirm the answer is yes the UK approval did follow the assessment report conducted by the Swedish Medical Products Agency. However, in line with guidance on repeat-use procedures, MHRA also conducted it's own evaluation based on the assessment report produced by Sweden and on regulatory dossier provided.

Further information about repeat-use procedures
The 'Repeat Use Procedure'(RUP) is the use of the Mutual Recognition Procedure (MRP) after the completion of a first MRP or Decentralised Procedure (DCP) for the recognition of a marketing authorisation by other Member States (MS). For the initial MRP, the Reference Member State (RMS) leads the administrative procedure and also prepares the Assessment Report (AR) which summarises the dossier and critically evaluates the safety, efficacy, and quality of the medicinal product. This AR is made available to all Concerned Member States (CMS) by the RMS and the CMS then base their evaluation of the dossier on the AR.

We trust that you will find this information of use. However, 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

Contact us | Swedish Medical Products Agency
Here you will find contact details and addresses of the Swedish Medical Products Agency.
Contact us | Swedish Medical Products Agency (lakemedelsverket.se)

Kind Regards,

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, January 17, 2024 5:02 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: CEC 174018 - Slynd (drospirenone progestogen-only contraceptive) PL 44081/0005

Dear Madam/Sir

Please can you send me a copy of the UK public assessment report for Slynd (drospirenone progestogen-only contraceptive) PL 44081/0005.

Was the UK market authorisation approval based on the assessment report conducted by the Swedish Medical Products Agency?

I look forward to hearing from you.

Many thanks.

Best wishes

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

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