Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

31 January 2023

Dear [redacted]

FOI 22/1132:

Thank you for your email, dated 03 November 2022, in which you requested information for Depo-Provera contraceptive injection - when it was approved for use by the MHRA and any studies relied upon at that time to make that decision.

Depo-Provera 150 mg/ml (PL 00057/0965) was granted a marketing authorisation in the UK to Pfizer Limited on 20 January 2012, following a change of authorisation holder (CoA). The original marketing authorisation for Depo-Provera 150 mg/ml (PL 00032/0082) was authorised on 27 August 1981 to Pharmacia Limited.

Depo-Provera 150 mg/ml (PL 00032/0082) was initially authorised as adjunctive therapy in certain classes of malignant tumours exhibiting a degree of hormone sensitivity. This marketing authorisation was supported by bibliographic data (literature references); no new clinical studies data were submitted. As the data submitted for the authorisation of this indication was published data in the form of bibliographic references, we are refusing to provide the submitted bibliographic data as its release is exempt under Section 21 (Accessible information accessible by other means) of the Freedom of information (FOI) Act.

A variation, referring to pre-existing data for Depo-Provera 50 mg/ml (PL 00032/0056), was granted on 01 October 1987 to extend the indications for Depo-Provera 150 mg/ml (PL 0032/0082) to include “use as a short-term anti-fertility agent and long-term contraceptive agent only in women in whom other methods were unsuitable”. We have searched our records (paper and electronic) for Depo-Provera 50 mg/ml (PL 0032/0056) and Depo-Provera 150 mg/ml (PL 00032/0082) and have not found the information you have requested (i.e. any studies relied upon) for this variation. Therefore, having exhausted all the

usual avenues in our search for this information, we have concluded that, it is no longer on our systems in a retrievable form.

A further variation to Depo-Provera 150 mg/ml (PL 00032/0082) was granted in December 1994, to allow long-term contraception in all women who had been appropriately counselled concerning the likelihood of menstrual disturbance and the potential for a delay in return to full fertility. This was in line with an application for Depo-Provera 150 mg/ml (PL 00032/0186), which was granted and subsequently cancelled in December 1994 once the variation to Depo-Provera 150 mg/ml (PL 00032/0082) was approved. Concerning your request for any studies relied upon for the grant of Depo-Provera contraceptive injection, we are providing the attached pre-clinical and clinical expert reports submitted for the application for Depo-Provera 150 mg/ml (PL 00032/0186) redacted under Section 40 of the Freedom of information Act. Please note that:

(i) the documentation has been redacted under Section 40 of the Freedom of Information Act. Disclosure of information subject to Section 40 (Personal information) would be an infringement of personal data. Section 40 (Personal information) is an absolute exemption and no consideration of the public interest is required.
(ii) the documentation is historical and variation applications may have been submitted subsequently to update some of the information included.

Please further note that a variation to remove the cancer indication and related statements was approved in July 1997.

We now consider this FOI request closed. If you have a query about this letter, please contact the MHRA FOI Licensing mailbox using the email address listed below.

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 2 months of the date you receive this response and addressed to: info@mhra.gov.uk, quoting reference FOI 22/1132.

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, and Cheshire, SK9 5AF.

Yours sincerely,

The FOI Licensing Team
Email: FOILicensing@mhra.gov.uk