Medicines & Healthcare products
Regulatory Agency

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[redacted]

16 January 2023

Dear [redacted]

FOI 22/1196:

Thank you for your email, dated 14 December 2022, in which you requested the clinical and non-clinical overview for Diazepam Desitin 5 mg and 10 mg Rectal solution (PL 14040/0001-0002).

Diazepam Desitin 5 mg and 10 mg Rectal solution (PL 14040/0001-0002) were granted as abridged simple applications on 10 February 1995, cross-referring to the medicinal products Diazepam RecTubes 5 mg and 10 mg (PL 04543/0340-0341).

We are responding to your request by providing the attached:

(i) expert reports on pharmaco-toxicological documentation and clinical documentation (equivalent to non-clinical and clinical overviews) submitted in support of the initial applications for Diazepam Desitin 5 mg and 10 mg Rectal solution (PL 14040/0001-0002-0001).
(ii) clinical overview submitted in support of the variation applications (PL 14040/0001-0035 and PL 14040/0002-0034) to update Section 4.6 of the Summary of Product Characteristics (SmPC) to include ‘neonatal nystagmus’.
(iii) clinical overview addenda submitted to support applications PL 14040/0001-0054 and PL 14040/0002-0053 to update the SmPC and the Patient Information Leaflet (package leaflet) in line with the Periodic Safety Update Report (PSUR) from the German regulatory authority.

Please note that:

(i) the expert reports (on pharmaco-toxicological documentation and clinical documentation) and clinical overview have 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.

In our follow-up response dated 04 January 2023 to FOI 22/1133, we stated that we had not located the non-clinical or clinical overviews for Diazepam RecTubes 5 mg Rectal Solution PL 04543/0340. On review, we have established that the attached expert reports on pharmaco-toxicological documentation and clinical documentation (equivalent to non-clinical and clinical overviews) also pertain to Diazepam RecTubes 5 mg Rectal Solution PL 04543/0340. We apologise for the omission.

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 22/1196.

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