FW: FOI 24/087

[redacted]

Hi all,

[redacted]

[redacted]

From: FOILicensing
Sent: Tuesday, February 20, 2024 12:29 PM
To: [redacted]
Subject: FOI 24/087

Dear [redacted]

Many thanks for your request for information, dated 26 January 2024, where you asked the following, further to our response to FOI 23/1000:

From your response, we are somewhat unclear as to the basis for the submission of the application Relaxit PL00009/0019 i.e. when you state that for Relaxit (PL 00009/0019) is 'based on a Product Licence of Right (PLR) for a product called Microlax (marketed since 1963), which the Marketing Authorisation Holder then renamed Relaxit', do you mean that the PLR was transferred to Pharmacia and renamed? Or was the application done on some other basis? We are aware that historically PLRs had to be transferred into PLs by submission of an updated dossier for full assessment, and seek to confirm our understanding that this was the case here?
In addition, please can you confirm the PLR number for Microlax and the MA Holder at that time? Finally, what was the date of grant of the Microlax PLR?

Our response:

The paper archive records for Relaxit (PL 00009/0019) indicate (within the documents submitted by the company) that it is based on a Product Licence of Right (PLR) for Microlax, but with a slightly different formulation, requiring submission of further data. The licence was not transferred to Pharmacia and renamed.

We have searched our records and cannot find record of a product named Microlax; we do not hold any information on a product by this name. There is, however, a product called Micralax and the reference to Microlax in the Relaxit submission documents is likely a typographical error. The licence for Micralax was granted as a PLR (PLR 00002/5037) to Smithkline & French Laboratories, on 29 November 1972. This then became a reviewed licence on 14 April 1988 (PL 00002/5037R).

Due to the age of the products mentioned, if you are trying to understand this information in order to develop your own product, it is advisable to apply for scientific advice to discuss any potential application further.

Details of our scientific advice procedure can be found in the link below:

Medicines: get scientific advice from MHRA - GOV.UK (www.gov.uk)

We now consider this request closed. 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
Or online via: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/"

Yours sincerely,
HQA FOI Team