Medicines & Healthcare products Regulatory Agency

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

[redacted]

06 December 2023

Dear [redacted]

FOI 23/753

Thank you for your communication, dated 10 October 2023, in which you requested the following, with respect to Levorol 5 mg/ml Oral Solution (PLGB 56809/0001), granted to Galvany Pharma Limited:

- Public Assessment Report (PAR)
- Nonclinical Overview, Module 2.4
- Clinical Overview, Module 2.5
- Clinical Summary, Module 2.7

MHRA response:
Levorol 5 mg/ml Oral Solution (PLGB 56809/0001) was authorised on 01 December 2022 to Galvany Pharma Limited, following a change of ownership procedure of Levorol 5 mg/ml Oral Solution (PL 39280/0016), which was granted to Synchrony Pharma Limited on 15 June 2022

With regard to your request for the PAR, we confirm that we hold this information; however, section 21(1) applies as this information is available on our website. We provide details below where you may access this information.

Please find attached the link for the published PAR for Levorol 5 mg/ml Oral Solution (PLGB 56809/0001) 5aa03bf5ab7baed082babc8e0a9bf9fc6c440c18 (windows.net).

Please also find attached the non-clinical overview, Module 2.4, and clinical overview, Module 2.5, submitted to support the initial application for Levorol 5 mg/ml Oral Solution (PL 39280/0016). The documentation has been redacted, with the related lists of literature references redacted and/or withheld, under Section 41 (Information given in confidence) and Section 43 (Commercial interests) of the Freedom of Information Act.

Section 41 (Information given in confidence) is an absolute exemption, and no consideration of the public interest is necessary, except to state that the release of this information withheld under this section of the FOI Act would be considered an actionable breach by the MHRA.

We have redacted some parts of the attached documentation under Section 43 (Commercial interests) of the FOI Act because the release of all, or part of, the information would, or would be likely to, cause harm to the third party's commercial interests. The exemption is to safeguard the commercially sensitive information/commercial enterprise. In this case, release of information would enable the competitors to overcome several regulatory hurdles in the research and development of their own products. This exemption is conditional on the public interest in releasing it not outweighing the company's/commercial enterprise's right to confidentiality and the probable damage that the company/commercial enterprise could suffer as a result of the information being released. We have considered the balance of the public interest when applying this exemption. In this case, we have not identified any issues which would benefit the public, as a whole, by being brought to their attention.

Please note that we do not hold a Clinical Summary, Module 2.7, for Levorol 5 mg/ml Oral Solution (PLGB 56809/0001), as none has been required or submitted.

We now consider this FOI 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 2 months of the date you receive this response and addressed to: info@mhra.gov.uk, quoting reference FOI 23/753.

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, and Cheshire, SK9 5AF.

Yours sincerely,

The FOI Team,
Healthcare Quality and Access.