Medicines & Healthcare products
Regulatory Agency

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United Kingdom
**gov.uk/mhra**

[redacted]

29 December 2023

Dear [redacted]

**FOI 23/861**

Thank you for your communication, dated 08 November 2023, in which you requested the clinical and non-clinical overviews for Axsain 0.075% w/w Cream (PL 16260/0016) and Zacin 0.025% w/w Cream (PL 16260/0028).

**MHRA response:**

A Marketing Authorisation for Axsain Cream 0.075% (PL 10670/0003) was granted on 20 August 1992 to Euroderma Limited for the symptomatic relief of neuralgia associated with and following Herpes Zoster infections (post-herpetic neuralgia) after open skin lesions have healed. A variation application for Axsain Cream 0.075% (PL 10670/0003-0004), in parallel with an initial application for Axsain Cream 0.075% (PL 10670/0010; Euroderma Limited), was approved on 22 November 1996 to include the indication 'symptomatic treatment of painful diabetic peripheral neuropathy'; on approval, the product licence PL 10670/0010 was cancelled.

A Marketing Authorisation for Axsain (PL 00041/0067) was granted to Bioglan Laboratories Limited on 18 December 1997 as a simple abridged application cross-referring to Axsain Cream 0.075% (PL 10670/0003), which was cancelled upon approval of PL 00041/0067. Following a series of change of ownership (COA) procedures of PL 0041/0067, including to Cephalon Limited (PL 21799/0002), the current Marketing Authorisation is held by Cephalon (UK) Limited (PL 16260/0016).

A Marketing Authorisation for Zacin Cream 0.025% (PL 10670/0011) was granted to Euroderma Limited on 27 January 1997 for the symptomatic relief of pain associated with osteoarthritis'. Following a series of change of ownership (COA) procedures of Axsain

Cream 0.075% (PL 10670/0003), including to Cephalon Limited (PL 21799/00014), the current Marketing Authorisation is held by Cephalon (UK) Limited (PL 16260/0028).

We are responding to your request by providing the attached:

**Axsain Cream 0.075%**

(i) The combined pharmacological/toxicological (non-clinical overview) and clinical expert report (clinical overview) submitted in support of the initial application for Axsain Cream 0.075% PL 10670/0003-0001, redacted under Section 40 of the FOI Act.
(ii) The pharmaco-toxicological expert report (non-clinical overview) and clinical expert report (clinical overview) submitted in support of the initial application for Axsain Cream 0.075% PL 10670/0010-0001, redacted under Section 40, Section 41 and Section 43 of the FOI Act.

**Zacin Cream 0.025%:**

(i) The pharmaco-toxicological expert report (non-clinical overview) and clinical expert report (clinical overview) submitted in support of the initial application for Zacin Cream 0.025% (PL 10670/0011-0001), redacted under Section 40, Section 41 and Section 43 of the FOI Act.
(ii) The clinical overview submitted to support the variation application for Zacin Cream 0.025% (PL 21799/0014-0008) to amend Section 4.8 of the Summary of Product Characteristic (SmPC), redacted under Section 40 of the FOI Act.

**Axsain Cream 0.075% and Zacin Cream 0.025%:**

(iii) The clinical overview submitted to support the variations for Axsain Cream 0.075% (PL 21799/0002-0010) and Zacin Cream 0.025% (PL 21799/0014-0010), to amend Section 4.4 of the SmPCs.
(iv) The clinical overview submitted to support the variations for Axsain Cream 0.075% (PL 21799/0002-0012) and Zacin Cream 0.025% (PL 21799/0014-0011) to amend Section 4.4 (Zacin Cream 0.25 % only) and Section 4.8 of the SmPCs.

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.

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.

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.

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 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.

Yours sincerely,

The FOI Team,
Healthcare Quality and Access.