PHARMAC
Pharmaceutical Management Agency

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16 April 2018

Via Email: fyi-request-7459-1d3afd64@requests.org.nz

Dear R Whyte

REQUEST FOR INFORMATION

Thank you for your request dated 16 March 2018 under the Official Information Act 1982 (OIA) for information on any and all bioavailability and pharmacodynamic studies that were submitted to or are held by PHARMAC for both the current and previous formulations of venlafaxine (Enlafax XR, Efexor XR and Arrow Venlafaxine XR).

The information that you have requested is publicly available and can be found in the data sheets published on Medsafe's website. Medsafe is the government agency responsible for the regulation (safety, quality and efficacy) of medicines in New Zealand, and PHARMAC relies on the data sheets Medsafe publishes on behalf of suppliers. As the medicines regulator, part of Medsafe's role is to review, in accordance with internationally recognised and accepted standards, the efficacy and safety of all formulations of venlafaxine before approving them for use in New Zealand. The links to the data sheets are as follows:

- Efexor XR: http://www.medsafe.govt.nz/profs/datasheet/e/Efexorxrcap.pdf
- Arrow Venlafaxine XR: http://www.medsafe.govt.nz/profs/Datasheet/a/arrowvenlafaxinexrtab.pdf
- Enlafax XR: http://www.medsafe.govt.nz/profs/Datasheet/e/enlafaxXRcap.pdf

It should be noted that PHARMAC has been given by one supplier, in confidence, a document on bioequivalence studies involving two brands of venlafaxine. As you may be aware, a bioequivalence study is the comparison of bio-availabilities of two different formulations of the same pharmaceutical form containing the same active ingredients. While it is unclear whether this report falls within the scope of your request, we have concluded that it may be within scope, and have reviewed it for release on that basis.

As a result of this review, PHARMAC has decided to withhold this document under section 9(2)(ba)(i) of the OIA as the withholding of the information is necessary to protect information which is subject to an obligation of confidence, where the making available of the information would be likely to prejudice the supply of similar information, or information from the same source, and it is in the public interest that such information should continue to be supplied.

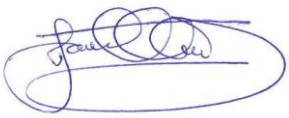
The report was sought to assist PHARMAC's decision-making when awarding a sole supply contract for this product. It was given to PHARMAC in confidence on the basis that it was to be used for internal purposes and not disclosed to external parties. Inability to maintain this obligation of confidence may negatively affect PHARMAC's future ability to procure products

at the best possible price and most favourable terms, which in turn affects public interests and health outcomes for the community.

As required under the OIA, we also considered whether, in the circumstances, the withholding of this information was outweighed by other considerations which render it desirable, in the public interest, to make this information available. In this case we did not consider that the public interest outweighed the reasons for withholding the information. Please note you have the right, by way of complaint under section 28(3) of the OIA to an Ombudsman, to seek an investigation and review of our decision.

We trust that the provision of this information answers your queries, if you have any further questions please feel free to contact us again.

Yours sincerely



Janet Mackay
Acting Director, Engagement and Implementation