MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

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Trudi Webber
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Ref: H201803736

Dear Ms Webber

Response to your request for official information

Thank you for your request of 8 May 2018 under the Official Information Act 1982 (the Act) for:

> *"I have read the information provided by Medsafe quoting all the research facts and figures regarding Enlafax, however it does not clearly state who did the research. Could you please tell me who and where the research was done? Was it research that the company selling the drug did or was it confirmed by independent researchers. This question should be answerable without breaking any confidence as it is not requesting how the product was made but how the research was conducted."*
>
> *"In response to your query dated 18th May 2018, my main questions "Could you please tell me who and where the research was done? Was it research that the company selling the drug did or was it confirmed by independent researchers?" are in relationship to the research quoted in the information provided by Medsafe which is their information sheet about Enlafax, on their website." [Follow up correspondence from 24 May 2018]*

In order to market a medicine in New Zealand, the sponsor of the medicine has to provide data to Medsafe to demonstrate that the medicine has acceptable quality, safety and efficacy. The sponsor of a medicine is the individual or company residing in New Zealand that is legally responsible for all aspects of the medicine. The first product using a new active ingredient to be approved in New Zealand is referred to as the innovator for that active ingredient. For venlafaxine, the innovator brand in New Zealand is called Effexor. As for all innovative medicines, clinical study data is required to show that the medicine is safe and efficacious. This clinical data is provided to Medsafe to determine if the medicine should be approved for the New Zealand market. The innovator medicine sponsor then provides a summary of these studies in the product data sheet, as shown in the Effexor data sheet published on the Medsafe website. A similar process occurs in other countries, such as the USA, EU and Australia. You can find more information on how Medsafe approves a medicine on the Medsafe website: http://www.medsafe.govt.nz/Medicines/approval-process.asp.

Once the patent for the innovator medicine has expired, other medicines using the same active ingredient are legally allowed to market medicines in New Zealand subject to Medsafe approval. These medicines are referred to as generic medicines.

For example, Enlafax XR and Arrow-Venlafaxine are both generic medicines containing venlafaxine. Generic medicines do not need to undergo the same clinical trials as the innovator medicine, as safety and efficacy for this active ingredient has already been established. It has been agreed internationally that generic medicines need to demonstrate that they are bioequivalent to the innovator medicine. Bioequivalence is determined when both the generic and innovator medicine for the same active ingredient produce statistically similar blood concentration levels following a fixed number of doses. For the approval of Enlafax XR, these studies were conducted in accordance with European Medicines Agency (EMA) guidance at the time of submission. The EMA guidance used to assess the acceptability of these studies are publically available on the EMA website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001768.jsp&mid=WC0b01ac0580b18a3a.

The clinical information presented within the Enlafax XR data sheet is based on the clinical data supplied by the sponsor of the New Zealand innovator product that was assessed by Medsafe prior to approval of Effexor XR. The clinical research conducted on the innovator product is considered relevant for Enlafax XR as it has been demonstrated to be bioequivalent to Effexor XR.

Additional information on clinical trials and the approval of Enlafax XR
Clinical studies are generally published in the scientific literature and on clinical trial registries for public access. You may find many of the clinical trials for Effexor on the US clinical trial registry: https://clinicaltrials.gov/ct2/home. Other agencies also review the data for medicines. For example, in the UK, NICE recommends that venlafaxine can be used if other anti-depressants are not effective. The Cochrane review group has also reviewed venlafaxine. You can access the reviews conducted by Cochrane through the Ministry of Health website.

Enlafax XR Modified Release Capsules have been approved in New Zealand since 12 March 2009. Enlafax XR has been approved for supply in a number of other countries, including the United States of America, Canada, United Kingdom, France and Australia. No significant issues regarding product quality have been identified by regulators in these countries for Enlafax XR.

I trust this information fulfils your request.

Yours sincerely

Chris James
Group Manager
Medsafe