Australian Government
Department of Health

DEPUTY SECRETARY

10 March 2016

Hayley Philpot
Coroners Registrar
Coroners Court of Victoria
65 Kavanagh Street
SOUTHBANK VIC 3006

cpuresponses@coronerscourt.vic.gov.au

Dear Ms Philpot

Investigation into the death of Dane A Hortle – Court reference COR 2012 000380

Thank you for your letter of 15 December 2015 addressed to the National Manager of the Therapeutic Goods Administration (TGA) providing the Deputy State Coroner's finding and recommendations following his investigation into the death of Dane Hortle.

Please note that a recent restructure in the Department of Health has resulted in the TGA being incorporated into the Regulatory Services Group and the position of National Manager of the TGA no longer exists. Future correspondence should be addressed to:

Adj. Professor John Skerritt
Deputy Secretary for Regulatory Services
Department of Health
PO Box 100
Woden ACT 2606 Australia

I am sorry to learn of the death of this young child and extend my sympathy to the family.

I have carefully considered your finding and recommendation that

> *The Therapeutic Goods Administration investigate the clinical need for Tramal Oral Drops in adults and paediatric patients above 12 years of age in order to determine whether it is appropriate to remove this medication from the Australian Register of Therapeutic Goods.*

The TGA was initially notified of Dane Hortle's death through an adverse drug reaction (ADR) report submitted by the sponsor of Tramal Oral Drops on 20 February 2013. Following subsequent receipt of further information from the sponsor, including information the sponsor had received from the Coroner, the TGA undertook a safety investigation of the product.

As a result of the investigation, the TGA concluded that:

- The product information clearly indicates that the product is only approved for use in children aged 12 years and over.
- Tramal Oral Drops is a formulation which is of value for adult patients who are unable to swallow other oral preparations of this medication, such as patients with neurological impairment or the terminally ill.
- The oral drops should remain available as a valuable presentation for pain relief in adult patients.

This investigation noted that use of the product by children under age 12 years is outside the TGA approval. This is known as "off-label use", the extent of which could not be accurately quantified. Prescribing a medicine 'off-label' is a decision by a health professional and is neither illegal nor within the scope of the TGA.

Subsequent to the investigation, the TGA worked with the sponsor to undertake a number of risk mitigation measures. These included:

- the Product Information (PI) and Consumer Medicine Information were updated to emphasise that the product is only approved for use in children aged 12 years and over
- the sponsor sent a letter to pharmacists reminding them of the age restriction
- the TGA published an article in the Medicine Safety Update of August 2015 to remind health professionals that tramadol oral drops are not approved for use in children under the age of 12 years. The article can be accessed on the TGA website at https://www.tga.gov.au/publication-issue/medicines-safety-update-volume-6-number-4-august-2015#tramadol

Following receipt of your formal recommendations, the TGA has again considered the issue of whether it would be appropriate to remove this product from the ARTG to prevent its use in children. We have concluded that the product meets a clinical need in adults who cannot swallow other oral preparations and that it would not be appropriate to remove the product from the ARTG.

We are currently considering possible additional communication activities to ensure wider distribution of the information about the age restriction for Tramadol Oral Drops.

Yours sincerely

Adj. Professor John Skerritt
Regulatory Services Group