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Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Mr Jeff Dart
Coroner's Registrar
Coroner's Court of Victoria
Level 11, 222 Exhibition Street
MELBOURNE 3000

Dear Mr Dart

Subject: Response to recommendation made by the coroner to the TGA in reference to Elsa Harrington, Court Ref: 3525/02

Thank you for providing the opportunity for the Therapeutic Goods Administration (TGA) to respond to the coroner's recommendation to the TGA in regard to the case of Elsa Harrington. In responding I will limit my comments to the following recommendation:

"The Therapeutic Goods Administration (TGA) update their bulletins and alerts on the risks associated with accidental paracetamol poisoning on the same grounds and that consideration be given to mandating improvements to consumer information to address the risks as identified in this investigation albeit that it is acknowledged the risk is small."

The TGA is responsible for regulating therapeutic goods including medicines, medical devices, blood and blood products. The TGA approves and regulates products based on an assessment of the risks against the benefits. In assessing the level of risk, the TGA takes into account factors such as side effects, potential harm through prolonged use, toxicity and the seriousness of the medical condition for which the product is intended to be used.

The TGA's approach to risk management involves identifying, assessing and evaluating the risks posed by therapeutic products; applying any measures necessary to minimise the risks posed; and monitoring and reviewing risks over time.

One of the measures that the TGA can take to minimise the risks associated with a medicine is to raise awareness of the risks. This can be done by publishing information on the TGA website and in the TGA's drug safety bulletin - *Medicines Safety Update* (MSU).

The first part of the coroner's recommendation, that the TGA update their bulletins and alerts on the risks associated with accidental paracetamol poisoning, will be implemented by the TGA. The TGA will undertake to update the information provided to health professionals and consumers on the TGA website within the next three months. The TGA will publish an article for health professionals in the August issue of MSU.

Furthermore, the TGA will undertake to collaborate with the National Prescribing Service (NPS) to assist in disseminating information to consumers on the risks of accidental paracetamol poisoning. The NPS is an independent, not-for-profit organisation funded by the Australian Government Department of Health and Ageing. Their purpose is to support the

best use of medicines to improve health and well-being and they have a number of ongoing programs which aim to provide consumers with the necessary information they need to make better decisions about medicines.

The second part of the coroner's recommendation, that consideration be given to mandating improvements to consumer information to address the risks as identified in this investigation, is under consideration by the TGA.

The Therapeutic Goods Act, Regulations and Orders set out the requirements for inclusion of therapeutic goods in the Australian Register of Therapeutic Goods, including the labelling requirements for medicines. Therapeutic Goods Order 69 – *General requirements for labels for medicines,* mandates that medicine labels must include the label advisory statements specified in the *Required Advisory Statements for Medicines Labels.*

The TGA is constrained by the current legislation with regards to its ability to mandate changes to medicine labels. Consideration will need to be given to additional mechanisms by which the TGA can improve consumer information. The implementation of any additional mechanisms will necessitate consultation both within the TGA and with industry and therefore may occur over an extended period of time.

Yours sincerely

Brian Richards

Dr Brian Richards
Acting National Manager
Therapeutic Goods Administration

26 March 2012