Australian Government
Department of Health

Deputy Secretary

Ms Colleen Bebbington
Coroner's Registrar
Coroners Court of Victoria
65 Kavanagh Street
SOUTHBANK VIC 3006

Dear Ms Bebbington

Re: Investigation into the death of Kathy Jelbart (COR REF - 2016 006193)

The Therapeutic Goods Administration (TGA) has reviewed Coroner Mr John Olle's Finding Without Inquest into the death of Kathy Jelbart. I am responding to the Coroner's recommendation:

1. that TPMT genotyping for the common alleles should be mandatory for patients prior to the commencement of thiopurine containing medications.

Currently, TPMT testing is not mandatory prior to the prescription of thiopurine medications (azathioprine, mercaptopurine, thioguanine), and there appears to be no Australian guideline on this topic. The use of TPMT testing prior to the prescription of a thiopurine is at the discretion of individual clinicians. Although the level of knowledge regarding TPMT testing among prescribers of these medications is expected to be high, the actual uptake of TPMT testing is unknown.

The current Australian Product Information documents for thiopurine medications mention the availability of TPMT testing, but make no recommendations regarding its use. The issue of TPMT testing prior to the use of thiopurine medications has not been reviewed recently by the TGA.

The TGA has a number of regulatory options available in response to medication safety issues. These include adding appropriate information and warnings to Product Information documents, educating prescribers and consumers around the safe use of medicines, and may involve placing restrictions on the use or availability of medicines. In order to select the appropriate action(s), the TGA relies on scientific evaluation of the available evidence.

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The Coroner's recommendation is under consideration. The TGA will review the available evidence for the appropriate place for TPMT testing prior to the use of thiopurine medications in the Australian context, including seeking the advice of appropriate external experts. The timeframe for a decision following this review is estimated to be twelve months. The relevant contact person responsible for the consideration of this recommendation is Dr Claire Behm: Claire.behm@health.gov.au; ph (02) 6232 8157.

Thank you for notifying the TGA of your recommendation.

Yours sincerely

Adj. Professor John Skerritt
Health Products Regulation Group

30 January 2018