Ref No: MC18-015441

Coroners Prevention Unit Coroners Court of Victoria 65 Kavanagh Street SOUTHBANK VIC 3006 17 JUL 2018

Dear Ms Chila

I refer to your letter of 28 June 2018 concerning the Coroner's finding into death without inquest of Graeme Griffiths. I regret the delay in responding.

I was sorry to learn of Mr Griffiths' death, which I understand was attributed to a rare side effect of his chemotherapy in the setting of probable dipyrimidine dehydrogenase deficiency. The Coroner has recommended that the Federal and Victorian Governments expedite the agreement for a single national repository for Vistogard (uridine triacetate), an antidote to the chemotherapy agents 5-Fluorouracil and capecitabine.

Vistogard (uridine triacetate) is not included in the Australian Register of Therapeutic Goods (ARTG) and therefore it has not been assessed by the Therapeutic Goods Administration (TGA) to ensure it meets certain standards of quality, safety and effectiveness. To be included in the ARTG, a sponsor is required to make an application to the TGA, which includes supporting evidence for its use.

Australian doctors can still lawfully access 'unapproved' products, such as Vistogard, for their patients through one of the schemes administered by the TGA, including the Special Access Scheme (SAS). In life threatening cases, the SAS Category A notification pathway is an existing mechanism to authorise supply of an 'unapproved' medicine without prior TGA approval. Vistogard has been previously supplied in Australia under the SAS.

I understand that it is common practice for hospitals or health services to maintain stock of antidotes (including 'unapproved' antidote products) in a central location because in most cases these need to be accessed rapidly. The decision of which emergency medicines are kept in hospitals is a matter for the individual health service and the relevant state or territory.

Thank you for bringing the Coroner's report to my attention.

Yours sincerely

Greg Hunt