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19 December 2017

Simon Shinkfield
Coroner's Registrar
Coroners Court of Victoria
65 Kavanagh Street
Southbank VIC 3006

Court Ref: COR 2015 004937

Dear Mr Shinkfield

Investigation into the death of Graeme H Griffiths

Thank you for the opportunity to respond to the Coroner's recommendation contained in COR 2015 004937 viz Peter MacCallum Cancer Centre "agree to establish and maintain a national repository for 'Vistogard'. We received your request on 29 November 2017.

Our response is outlined below, consistent with the guidelines for responding to Coroner's recommendations and within the time frame required by section 72(3) of the Coroners *Act* 2008 (Vic).

Recommendation
That the Peter MacCallum Cancer Centre agree to establish and maintain a national repository for 'Vistogard'.

Response
There are unresolved issues with the Coroner's recommendation that need to be addressed.

The Issues

1. The drug, uridine triacetate (**Vistogard®**) is not currently approved for use in Australia however it can be accessed via the Special Access Scheme for use on a case by case basis. It is FDA approved as an 'orphan drug' which means the market for this agent is small, and the company (Wellstat) is not expected to recover the costs of developing/marketing this drug. It is not clear if Wellstat will submit for Australian TGA approval.

   Wellstat administers the access program for this drug. It is provided on a named patient basis once a case of suspected 5FU-toxicity or capecitabine-toxicity has been substantiated. Under the current arrangements, any US or Australian hospital seeking to use this antidote is charged for the courier costs (for Australia, this is typically US$8k) but not the cost of the drug.

2. Although it is utilized infrequently, Vistogard is the sole treatment for life-threatening capecitabine/5FU toxicity and the chances of survival are significantly improved with this antidote. Acceptance onto the named patient program or eligibility for access to Vistogard is conditional on being able to commence treatment with Vistogard within 96 hours after 5FU or capecitabine

cessation. Currently, it requires urgent administrative action and 48hours to ship from the USA. Peter MacCallum Cancer Institute has needed to access this drug twice in the last year.

3. Peter Mac currently acts as the Australian repository for, glucarpidase (Voraxaze®) that is used for methotrexate toxicity,. Glucarpidase (Voraxaze®), is also not TGA approved but is accessible via the Special Access Scheme. This has been a long standing arrangement (over 10 years) to facilitate rapid access to life-saving treatment. Although Vistogard and glucarpidase serve different purposes, the experience with glucarpidase has demonstrated the feasibility and utility of a central drug repository.

4. Peter Mac is willing to become the national repository for Vistogard under the current Special Access Scheme. However, any distribution model and provision/sustainment of drug assignment will require approval from the drug company, Wellstat, which has not been granted at this time. Wellstat is striving to increase the availability of the drug in Australia in 2018.

5. Peter MacCallum Cancer Institute is willing to become the national repository for uridine triacetate (Vistogard®) but this will require approval from the drug company Wellstat of a distribution model for Australia.

6. Please do not hesitate to contact me should you require further information.

Yours sincerely

Elizabeth Kennedy

Elizabeth Kennedy
General Counsel and Corporate Secretary