

**Response to Coroner's Recommendation following the investigation into the death of the**  
[REDACTED] **(deceased)**

**Reference number: COR2018005623**

**Pursuant to Section 72 3 of the Coroner's Act 2008 (Vic)**

Peter MacCallum Cancer Institute provides the following written response to the recommendation of the Coroner made following the investigation into the death of [REDACTED] on 31 October 2018.

One of the key issues for the finding into her death without inquest was toxicity to capecitabine and the availability of an antidote in Australia. The routine testing for DPD deficiency has been debated for a long time.

Peter MacCallum Cancer Institute is now testing all patients prior to their undergoing fluoropyrimidine based chemotherapy (including capecitabine and 5FU) as recommended by the European Medicines Agency, but the FDA do not recommend routine testing. The type of testing is also a challenge. Testing for the 4 major genotypic variants only accounts for up to 25% of DPD deficient patients. Phenotypic tests could detect a higher proportion of cases, but there is no suitable test available for widespread use. The Coroner has recommended that Peter Mac and Medical Oncology Group of Australia (MOGA) make a joint submission to the Medical Services Advisory Committee (MSAC) to consider the feasibility of funding DPYD testing for all patients prior to commencement of fluoropyrimidines in Australia and determine the support required to implement a DPYD testing programme to remove the major barrier of cost to testing to provide oncologists and patients the choice to undertake DPYD testing when clinically indicated. As stated above, Peter MacCallum Cancer Centre, is testing all patients prior to the commencement of fluoropyrimidines. Peter Mac has approached both MOGA and MSAC (through its chair) to ascertain how the Coroner's recommendation might be best implemented. The response from MSAC, albeit informally, is that for pathology tests such as DPYD testing the usual Sponsor would be the Royal Australian College of Pathologists or a commercial pathology laboratory. They suggested that Peter Mac and MOGA write instead to the Health Technology Assessment team of MSAC within the Department of Health who would then do an evaluation and if there was support for the suggestion made by the Coroner, would then seek a sponsor. It is submitted that it is not for Peter Mac or MOGA to act as sponsor and to collect the evidence and make the submission to government. Peter Mac will write to the Health Technology Assessment team to request an assessment. Please do not hesitate to contact me should they require further information or response.



**Elizabeth Kennedy**  
**General Counsel and Corporate Secretary**  
**Peter MacCallum Cancer Centre**

Cc: Associate Professor Danny Rischin