Australian Government

Department of Health

Deputy Secretary

Ms Dawn Wright
Office of the State Coroner
Level 10, Central Law Courts
501 Hay Street
PERTH WA 6000

Dear Ms Wright

Re: Inquest into the death of Stephen Michael KELL (Ref: 37/19)

I am writing in response to Coroner Fogliani's recommendation:

I recommend that Pfizer Australia and Mylan Australia, in consultation with the Therapeutic Goods Administration, consider highlighting the risk of clozapine-induced gastrointestinal hypomotility in the boxed warning that appears at the beginning of their Product Information, and that if so altered, that it appears in the MIMS Full Prescribing Information and the Consumer Medicine Information.

In 2018, the Therapeutic Goods Administration (TGA) published a warning that clozapine-induced gastrointestinal hypomotility can result in serious consequences, including death (www.tga.gov.au/publication-issue/medicines-safety-update-volume-9-number-2-june-2018#a3). The warning was also added to the Product Information of clozapine products. However, in view of the continued reporting of serious outcomes related to this adverse event, the TGA will further review this issue with a view to deciding if further Product Information updates (including a boxed warning) are needed. We will respond further once the review is complete, estimated to be in six months.

Thank you for notifying the TGA of the Coroner's recommendation.

Yours sincerely

Adj. Professor John Skerritt
Health Products Regulation Group

September 2020

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