Australian Government

Department of Health and Aged Care

Deputy Secretary

Dr Jeyanthi Kunadhasan
Treasurer
Australian Medical Professionals' Society
41 Campbell Street
BOWEN HILLS QLD 4006

Dear Dr Kunadhasan

Thank you for your letter, dated 21 March 2024, concerning undisclosed deaths in C4591001 Trial.

First, I would like to clarify that while the Therapeutic Goods Administration (TGA) does work closely with international counterparts, including the US Food and Drug Administration (FDA), the TGA independently reviews data submitted as part of a submission to register a medicine or vaccine, and makes its own decision based on the Australian context. Questions pertaining to the FDA's conduct of its own investigations are best directed to the FDA itself.

Second, the TGA is not aware of any 'hidden deaths'. At the time of provisional approval, the interim report provided to the TGA included 6 deaths. This is articulated on page 29 of the Australian Public Assessment Report (AusPAR) for COMIRNATY (accessible at: www.tga.gov.au/sites/default/files/auspar-bnt162b2-mrna-210125.pdf). Subsequently, the final report of the trial, with updated figures on safety outcomes including deaths over the 6-month double-blind period and subsequent open-label follow-up, has been provided to the TGA.

Large, multicentre clinical trials in humans present complex logistic challenges and despite preplanned protocols, detailed procedures and strict monitoring, similar errors and protocol deviations are commonly reported in clinical trials. These are not considered a breach of Good Clinical Practice or 'hidden deaths'. The subsequent reports or supplementary addenda capture or correct any missing or incorrectly reported data and if needed revised reports are issued.

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It is reassuring to note that, in this case, none of the deaths in the trial have been attributed to the vaccine and the initial conclusions remain valid. The accumulating published evidence over time continues to support the significant public health benefit of the safety and efficacy of mRNA vaccines, as well as an overwhelmingly favourable risk/benefit ratio.

I would like to emphasise that the TGA takes the issue of data integrity very seriously. It is not possible to audit all clinical trials routinely, however random or targeted inspections are conducted when appropriate. In addition, information is shared across various regulators where significant issues are suspected. In the case of this clinical trial, there has not been any evidence or suggestion of impropriety that would have required such action or revision of findings.

I thank you for your effort in corresponding and hope to have addressed your concerns.

Yours sincerely

Professor Anthony Lawler
Health Products Regulation Group

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