Australian Government

Department of Health

Deputy Secretary

Mr Robert Cockburn
Unit 3
36 Hampden Road
ARTARMON NSW 2064

Dear Mr Cockburn

I refer to your correspondence of 13 May 2022, requesting that I investigate the conduct of my staff in relation to a clinical trial involving two medical devices.

I take seriously any suggestion of wrongdoing by TGA staff. I have looked into this matter and I am confident that there has been no misconduct by my staff.

Since 2019, the TGA has responded to multiple enquiries from you relating to the conduct of the clinical trial you participated in and the medical devices it used. I acknowledge that some of the information provided to you in 2019 regarding the registration status of the devices used in the clinical trial you participated in may have been incomplete or unclear. However, I am satisfied that no staff have deliberately provided you with false information or withheld relevant information.

As we have previously confirmed, the Spiro-PD made by PMD Healthcare, PA, USA was included in the Australian Register of Therapeutic Goods (ARTG) under the number 193592 between 6 January 2012 and 27 February 2017. The product was cancelled on 27 February 2017 at the request of the sponsor as noted on our website: www.tga.gov.au/ws-sc-index.

On 20 December 2019 the spirometer made by PMD Healthcare was re-included on the ARTG under the number 327977. I am satisfied that the application for this device was reviewed in a manner consistent with usual procedures for a Class IIa medical device, whose application is supported by European Union medical device certification. It was subsequently cancelled by the sponsor on 5 August 2021.

Phone: (02) 6289 4200 **Email:** John.Skerritt@health.gov.au
PO Box 100 Woden ACT 2606 - **www.health.gov.au**

I am sorry to hear that you experienced respiratory and neurological conditions, following your participation in the clinical trial. I note that you first reported these harms to us on 24 January 2019, and I thank you for reporting your experiences to us. The TGA uses reports about adverse events to identify potential safety issues with medical devices that may require regulatory action. However, the TGA's monitoring has not identified a safety issue relating to the Spiro-PD. Apart from your correspondence, we have received no other incident reports on this device.

I understand that 13 emails have been received from you since January 2019 by the Department of Health, including TGA, which were responded to by TGA, or the Minister for Health. As we have confirmed in our past correspondence, the TGA regulates access to unapproved goods used in clinical trials through the Clinical Trial Notification (CTN) and Clinical Trial Approval (CTA) pathways available at www.tga.gov.au/clinical-trials.

The CTN pathway is a notification process. The TGA does not evaluate any data relating to the investigational products at the time of the notification. The CTN pathway requires that all materials relating to the proposed trial, including the trial protocol, Patient Information and Informed Consent Form, are submitted to a Human Research Ethics Committee (HREC) by the researcher. It is the role of the HREC to assess, evaluate and monitor the trial. All clinical trials require HREC approval before the clinical trial may commence. HRECs play a central role in reviewing clinical trials that are subject to the therapeutic goods legislation.

As you have previously been advised, the following bodies can assist in reviewing conduct of healthcare professionals:

- Australian Health Practitioner Regulation Agency (AHPRA) www.ahpra.gov.au/notifications/make-a-complaint.aspx
- Health Care Complaints Commission in NSW www.hccc.nsw.gov.au/

Yours sincerely

Adj. Professor John Skerritt
Health Products Regulation Group

24 June 2022