Australian Government

Department of Health

Deputy Secretary

Mr Jason Lange
Executive Director
Office of Best Practice Regulation
Department of the Prime Minister and Cabinet
Email: helpdesk-OBPR@pmc.gov.au

Dear Jason

Remaking of the Therapeutic Goods (Multi-Site Manufacturing Licences) Guidelines

I am writing regarding the Therapeutic Goods (Multi-Site Manufacturing Licences) Guidelines of 2010 (the former Guidelines) that were due to sunset on 1 April 2020 under the sunsetting provisions of the *Legislation Act 2003.* We have reviewed the former Guidelines and decided that the legislative instrument is still required but that they be remade as the *Therapeutic Goods (Guidelines for Multi-Site Licences) Instrument 2020* (the Guidelines Instrument) without significant amendment.

The Department of Health certifies that the former Guidelines were operating effectively and efficiently, and a Regulation Impact Statement is not required to remake this regulation. Our assessment was informed by a targeted consultation process with affected manufacturers and industry representatives through the TGA-Industry Working Group on Good Manufacturing Practice, the International Society of Cell and Gene Therapy, the Biotherapeutics Association of Australasia and the Australian Red Cross Lifeblood.

Consultation was conducted during January and February 2020 where we sought feedback on the continued fitness and relevance of the former Guidelines, and its proposed re-making as the Guidelines Instrument. The responses received were all in agreement with reissuing the guidelines without amendment.

I apologise for the delay in providing you the certification. I acknowledge that OBPR will publish this letter for transparency purposes. If you have any queries about this advice, please contact Ms Tracey Duffy, First Assistant Secretary, Medical Devices and Product Quality Division on 02 6289 4230, or tracey.duffy@health.gov.au.

Yours sincerely

Adj. Professor John Skerritt
Health Products Regulation Group

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