



Enquiries to: Melissa Hagan
Director
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File Ref: C-ECTF-22/6858

Queensland Health

Mr Herschel Baker
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Queensland Director, Drug Free Australia
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Dear Mr Baker

Thank you for your email to the Hon Annastacia Palaszczuk MP, Premier of Queensland and Minister for the Olympics, dated 1 April 2022, regarding concerns about the oversight of the Therapeutic Goods Administration (TGA). The Minister has asked that I respond directly to you on this occasion.

I note that since the introduction of the Clinical Trial Notification Scheme (CTN) in 1991, clinical trials in Australia have been conducted safely including clinical trials within Queensland Health.

To further support safe clinical trial conduct, it is important to note that the TGA regulates clinical trials of medicines and biologicals regulated under the CTN or Clinical Trial Approval (CTA) schemes and are subject to the TGA's Good Clinical Practice (GCP) Inspection Program. The TGA has published guidance on the GCP Inspection Program to provide clinical trial sponsors with further information about the Program's scope and process.

Further advice can be requested from the TGA regarding the findings from the TGA Inspection Program.

Should you require any further information in relation to this matter, I have arranged for Ms Melissa Hagan, Director, Office of Precision Medicine and Research, Department of Health, on telephone (07) 3708 5077, to be available to assist you.

Yours sincerely

Professor Keith McNeil
**Acting Deputy Director-General and
Chief Medical Officer, Prevention Division and
Chief Clinical Information Officer
Queensland Health**

27 / 05 / 2022