

Ben Clemens

From: FRANCIS, Jenny <Jenny.Francis@health.gov.au>
Sent: Monday, 22 February 2021 12:44 PM
To: Ben Clemens
Subject: People for Safe Vaccines Pty Ltd and Commonwealth of Australia [SEC=OFFICIAL]
Attachments: 210202 - Ltr to DoH.pdf

Importance: High

Dear Mr Clemens

Thank you for your letter of 2 February. I regret the delay in response.

Your representation for the 'TGA documents' to be amended, relevant information conveyed to healthcare providers and consumers and other information to be published are noted.

The questions posed in [19(a), (c) and (d)] of your letter, raise issues which are commercial in confidence to the parties involved including the Commonwealth for which there is no authority to disclose.

For your query at [19(b)] about the [Therapeutic Goods \(Poisons Standard\)\(COVID-19 Vaccine Pfizer\) Labelling Exemption 2021](#); in the first instance, the Pfizer vaccine is imported into, and supplied in, Australia with international labels, necessitating the exemptions. The notes at the foot of s 5 of the Exemption explain the provisions in the Poisons Standard from which the Pfizer vaccine is exempt. They are provisions dealing with labelling on the primary pack, the information for which is otherwise unnecessary when the medicine is exclusively administered by medical practitioners, for example 'Keep out of reach of children' or which is otherwise made available to those administering the vaccine, for example the approved name of the vaccine.

Kind regards

Jenny

Jenny Francis

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The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.