THE GLOBAL AVIATION ADVOCACY COALITION

To:

Air Chief Marshal (Retd) Mark Binskin AC, Chair of the Board
Ms. Pip Spence PSM, Chief Executive Officer & Director of Aviation Safety
Mr. Michael Bridge
Ms. Donna Hardman
Ms. Elizabeth Hallett GAICD
Ms. Marilyn Andre
Dr. Felipe Gonzalez
Dr. Kate Manderson
Dr. Tony Hochsberg
Australian Civil Aviation Safety Authority
Aviation House
16 Furzer Street
Phillip ACT 2606

21st July 2022

From: **The Global Aviation Advocacy Coalition:** gaacoalition@protonmail.com

Dear CASA Board Members and Medical Officers,

RE: **Covid-19 Vaccination and Class 1-3 Medical Certificate Holders**

Thank you for your kind reply dated 14 July 2022, it is indeed helpful and greatly appreciated.

Further to that reply, please can you provide further insight into the following questions:

1. As you have advised us that CASA defers to the TGA in respect of Covid-19 vaccine safety monitoring:
   a) Does CASA have any form of its own definition of "safety" or "efficacy" of the Covid-19 vaccines, outside of which it would independently withdraw their use by Class 1-3 medical certificate holders? If so, what are those definitions?
   b) Does CASA's deference to the TGA in this regard effectively mean that TGA assessments, decisions, recommendations etc fully cascade, unimpeded, through CASA and into its medical system?
   c) By what means would any TGA error or inappropriate determination of Covid-19 "vaccine" classification, safety, efficacy or suitability for use by Class 1-3 medical certificate holders, be avoided, trapped or mitigated by CASA?
   d) How does the TGA's processes take specific account of aviation medicine when it comes to Covid-19 vaccines and, if CASA defers to it, how has CASA ensured that TGA has fully accounted for all possible aviation medicine considerations/risks etc specific to the aviation environment?
   e) What specific Covid-19 vaccine trial data has CASA examined for each of the Covid-19 vaccines?
   f) What specific Covid-19 vaccine surveillance data/evidence/reports does CASA examine and what is the process by which it evaluates them?
2. You state that "the SARS-CoV-2 vaccines available in Australia have been approved for use by the TGA and are therefore treated by CASA the same as any other immunisation." No Covid-19 vaccine has been fully approved. They are all subject to Provisional Determination Notices and are provisionally approved for use. TGA states:

   > *"The [provisional] approval is subject to certain strict conditions, such as the requirement for [manufacturer] to continue providing information to the TGA on longer term efficacy and safety from ongoing clinical trials and post-market assessment."*
   >
   > *"**Many of the large-scale clinical trials that will provide evidence of safety and effectiveness are still progressing** and these results will be provided to the TGA as they become available. The TGA will also evaluate quality data (such as how the vaccines are manufactured). The TGA will only be in a*

position to make a provisional registration decision for a vaccine once all required data relating to safety, quality and efficacy has been provided and assessed. With rolling submissions, collaboration with international regulators, and proactively working with sponsors, it is expected the evaluation of COVID-19 vaccines will be significantly expedited without compromising on our strict standards of safety, quality and efficacy. However, the timeframe for the evaluation of each vaccine will ultimately depend on when the complete data package is provided by sponsors. ***We have not yet received a full data package from any company.****" (source* https://www.tga.gov.au/covid-19-vaccines-undergoing-evaluation)

What significance does such conditionality, ongoing trials and lack of full data have on CASA's view of medical products in use under provisional authorisation in the aviation industry?

3. Which other drugs, medical devices, treatments, vaccines or immunisations for diseases other than Covid-19 that CASA allows Class 1-3 medical holders to use have the same provisional authorisation, status and conditions as Covid-19 vaccines?
4. In CASA's opinion, is it possible for a Class 1-3 medical certificate holder to have suffered a vaccine-induced injury that, for some reason, is not formally attributed to a vaccine and therefore never recorded as such in CASA medical system e.g. causal misdiagnosis, refusal by clinician to entertain a vaccine as a cause for some reason (including prejudice or lack of knowledge)? If so, could it be possible that CASA might not ever know of or recognise such issues?
5. How does CASA become aware of any possible vaccine related injury amongst medically-certified personnel?
6. Should a Class 1-3 medical certificate holder choose to withhold information about an actual or suspected medical condition from CASA, how would CASA know unless the individual was effectively "found out" via involvement in incident, accident or third party reporting?
7. Should a Class 1-3 medical certificate holder wish to take part in a Covid-19 vaccine clinical trial of any kind, for example a booster "mix-and-match" trial, how would they have to interact with CASA to do so legally and in conformance with their regulatory and licence obligations? Would they have to: declare their intent to do so to CASA; be granted permission by CASA? Would the individual be able to take part in such a trial and still continue to operate flights in accordance with their licence?

We thank you for your anticipated efforts in providing your insight into the above questions and look forward to receiving your reply by email in due course.

Yours sincerely,

Greg Hill, Director
Free to Fly
Canada

Josh Yoder, President
US Freedom Flyers
USA

Philippe Pelletier, President
Navigants Libres
France

Mark Juch, Chairman
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Netherlands

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Katarina Lindley, D.O, FACOFP
Cofounder, CAIM
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Dr. Elizabeth Evans
UK Medical Freedom Alliance
United Kingdom

Jennifer Hibberd, DDS
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International

Pete Chambers, LTC, DO
MC, FS, SF
US Special Ops Flight Surgeon

Jane M. Orient, MD, Exec Director
Association of American Physicians
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The new look TGA website will be ready soon – For more details visit our project page at

TGA Website Redevelopment 2022 (//www.tga.gov.au/tga-website-redevelopment-2022)

Australian Government
Department of Health
Therapeutic Goods Administration

COVID-19 vaccines undergoing evaluation

19 July 2022

Before any COVID-19 vaccine is approved for use in Australia, it will be subject to the well-established and rigorous assessment and approval processes of the Therapeutic Goods Administration (TGA), part of the Department of Health.

The TGA has received applications and is assessing preliminary data for the following COVID-19 vaccines using the provisional pathway (//www.tga.gov.au/provisional-approval-pathway-prescription-medicines) and rolling review procedures.

Sponsor	Name	Type	Further information	Regulatory status
Grand Pacific CRO Australia (on behalf of Medigen Vaccine Biologics Corp)	MVC COVID-19 vaccine (MVC-COV1901)	Protein subunit	Provisional determination notice (//www.tga.gov.au/tga-grants-provisional-determination-grand-pacific-cro-australia-behalf-medigen-vaccine-biologics-corp-its-covid-19-protein-based-subunit-vaccine)	Application for vaccination for adults aged 18 years and older under evaluation.

Sponsor	Name	Type	Further information	Regulatory status
Moderna Australia Pty Ltd	SPIKEVAX Bivalent Zero/Omicron (elasomeran/elasomeran 0- omicron)	mRNA	Provisional determination notice (//www.tga.gov.au/media-release/tga-grants-provisional-determination-moderna-bivalent-covid-19-vaccine-spikevax-bivalent-zeroomicron)	Application for use in adults aged 18 years and older under evaluation.

Sponsor	Name	Type	Further information	Regulatory status
Moderna Australia Pty Ltd	SPIKEVAX (elasomeran)	mRNA	Provisional Determination Notice (//www.tga.gov.au/media-release/tga-grants-provisional-determination-moderna-covid-19-vaccine-elasomeran)	a. Provisionally approved on 9 August 2021 for adults aged 18 years and over. b. Provisionally approved on 3 September 2021 for individuals aged 12-17 years. c. Booster dose provisionally approved on 7 December 2021 for individuals aged 18 years and over. d. Provisionally approved on 17 February 2022 for individuals aged 6-11 years. e. Application for booster dose for individuals aged 12 years and over under evaluation.

Sponsor	Name	Type	Further information	Regulatory status
				f. Provisionally approved on 19 July 2022 for individuals aged 6 months to less than 6 years
Biocelect Pty Ltd on behalf of Novavax Inc	NUVAXOVID	Protein vaccine	Provisional determination notice (//www.tga.gov.au/tga-grants-additional-provisional-determination-covid-19-vaccine)	a. Provisionally approved on 19 January 2022 for individuals aged 18 years and over b. Booster dose provisionally approved on 9 June 2022 for individuals aged 18 years and over. c. Application for extension of indication to include individuals aged 12-17 years under evaluation.

Sponsor	Name	Type	Further information	Regulatory status
Janssen-Cilag Pty Ltd	COVID-19 Vaccine Janssen	Viral vector	Provisional determination notice (//www.tga.gov.au/tga-grants-third-provisional-determination-covid-19-vaccine)	Provisionally approved on 25 June 2021 for individuals aged 18 years and over.

Sponsor	Name	Type	Further information	Regulatory status
Pfizer Australia Pty Ltd	COMIRNATY - (tozinameran) [mRNA]	mRNA	Provisional determination notice (//www.tga.gov.au/tga-grants-second-provisional-determination-covid-19-vaccine)	a. Provisionally approved on 25 January 2021 for individuals aged 16 years and over. b. Provisionally approved on 22 July 2021 for individuals aged 12-15 years and over. c. Booster dose provisionally approved on 26 October 2021 for individuals aged 18 years and over. d. Provisionally approved on 3 December 2021 for individuals aged 5-11 years. e. Booster dose provisionally approved on 27 January

Sponsor	Name	Type	Further information	Regulatory status
				2022 for individuals aged 16-17 years. f. Booster dose provisionally approved on 7 April 2022 for individuals aged 12-15 years. g. Application for booster dose for individuals aged 5-11 years under evaluation.
AstraZeneca Pty Ltd	VAXZEVRIA (previously COVID-19 Vaccine AstraZeneca)	Viral vector	Provisional determination notice (//www.tga.gov.au/tga-grants-provisional-determination-covid-19-vaccine)	a. Provisionally approved on 15 February 2021 for individuals aged 18 years and over. b. Booster dose provisionally approved on 8 February 2022 for individuals aged 18 years and over.

All COVID-19 vaccine applications are being treated with the greatest priority as part of the Department of Health's response to the pandemic. Under normal circumstances, TGA's assessment (for both provisional and general registration) begins once all information to support registration is available. For COVID-19 vaccines, the TGA has agreed to accept rolling data to enable early evaluation of data as it comes to hand.

Many of the large-scale clinical trials that will provide evidence of safety and effectiveness are still progressing and these results will be provided to the TGA as they become available. The TGA will also evaluate quality data (such as how the vaccines are manufactured).

The TGA will only be in a position to make a provisional registration decision for a vaccine once all required data relating to safety, quality and efficacy has been provided and assessed.

With rolling submissions, collaboration with international regulators, and proactively working with sponsors, it is expected the evaluation of COVID-19 vaccines will be significantly expedited without compromising on our strict standards of safety, quality and efficacy. However, the timeframe for the evaluation of each vaccine will ultimately depend on when the complete data package is provided by sponsors. We have not yet received a full data package from any company.

Further information on the TGA's evaluation process for vaccines is available at: COVID-19 vaccine approval process (//www.tga.gov.au/covid-19-vaccine-approval-process).

Emergency use of vaccines in other countries

The TGA is aware that other countries may consider exercising emergency use provisions that allow access to unapproved vaccines prior to formal regulatory approval based on assessment of early safety and efficacy data. Exercising these provisions is a matter for those countries, taking into account the risks versus benefits in the context of the prevailing domestic pandemic situation.

Tags: COVID-19 vaccines, vaccines
URL: https://www.tga.gov.au/node/934643 (https://www.tga.gov.au/node/934643)