16 December 2021

Dr Brendan Murphy
Secretary, Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

By Email: covidvaccineenquiries@health.gov.au;
enquiries@health.gov.au;
info@tga.gov.au

Dear Sir,

RE: PROVISIONAL REGISTRATION OF COVID-19 VACCINES

With reference to the above matter, the Australian Vaccine-risks Network, Inc. ("the AVN") has previously communicated with the Department of Health regarding the following provisional approval registrations:

a. The VAXZEVRIA (previously COVID-19 Vaccine AstraZeneca) vaccine registration held by AstraZeneca Pty Ltd effective from 15 February 2021;

("the AZ Registration")

b. The COMIRNATY – BNT162b2 [mRNA] vaccine registration held by Pfizer Australia Pty Ltd effective from 25 January 2021 and extended on 22 July 2021 and 26 October 2021.

("the Pfizer Registration")

c. The Spikevax vaccine held by Moderna Australia Pty Ltd effective from 9 August 2021 and extended on 3 September 2021.

("the Moderna Registration" and collectively, "the Registrations" and "the vaccines")

The communications regarding the Registrations were as follows:

a. A letter sent on 27 May 2021 which received a response from a Director of the Department of Health with reference number MC21-016199; and
b. A letter sent on 26 November 2021.

We have attached copies of the above communications for your reference.

The AVN believes the Registrations ought to have been suspended or cancelled on the non-exhaustive basis that there is information and evidence that each of the Registrations have caused historically unprecedented adverse events including deaths, illnesses and injuries that warrant suspension or cancellation and that insufficient weight has been placed on that information.

The AVN wishes to impress the urgency of our belief based on the harm or potential harm including death, illness, or injury that may be suffered as a consequence of adverse reactions to the vaccines:

a. In persons 'fully vaccinated' by any definition;
b. In persons 'partially vaccinated' by any definition;
c. In persons 'partially vaccinated' contemplating further receiving one or more of the vaccines;
d. In persons unvaccinated but contemplating receiving one or more of the vaccines; and
e. In children aged five (5) through eleven (11) based on the TGA announcement that the Pfizer Registration has been approved for same from 10 January 2022.

The AVN must impress upon the Secretary of Health that the continued registration of the vaccines is untenable in light of the considerations required of the Secretary in respect of the post-marketing safety surveillance data received by the Therapeutic Goods Administration ('the TGA') from:

a. Australian Adverse Event reports; and
b. Adverse Event reporting systems in other countries the TGA shares such data with, and accesses, including the VAERS system in the USA; and
c. The Uppsala Monitoring Centre ('the UMC'); and
d. The VigiAccess system jointly managed by the UMC and the World Health Organisation ('the WHO'); and
e. Adverse Event reports held by the TGA received from, provided by, and requested from, including those capable of being requested from, the Australian sponsors of the vaccines; and
f. Published peer reviewed papers from any jurisdiction that address any relevant safety considerations, results, concerns, and/or conclusions discovered to have arisen in relation to the vaccines post-marketing; and
g. Any other available and relevant information informing the Pharmacovigilance duties and responsibilities of the Secretary and TGA.

The data from the above non-exhaustive sources directly serves to inform the considerations required of the Secretary under s22F(1) and s30(1)(a) and s30(2)(a) of the *Therapeutic Goods Administration Act* ('the Act'), which read:

Section 22F(1):
The Secretary may revoke a provisional determination under section 22D relating to a person and a medicine if the Secretary is satisfied that the criteria prescribed by the regulations for the purposes of subsection 22D(2) are no longer met in relation to the medicine.

Section 30(1)(a):
The Secretary may, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if:
(a) It appears to the Secretary that failure to cancel the registration or listing would create an imminent risk of death, serious illness or serious injury.

Section 30(2)(a):

Subject to subsection (3), the Secretary may, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if:

(a) It appears to the Secretary that the quality, safety or efficacy of the goods is unacceptable.

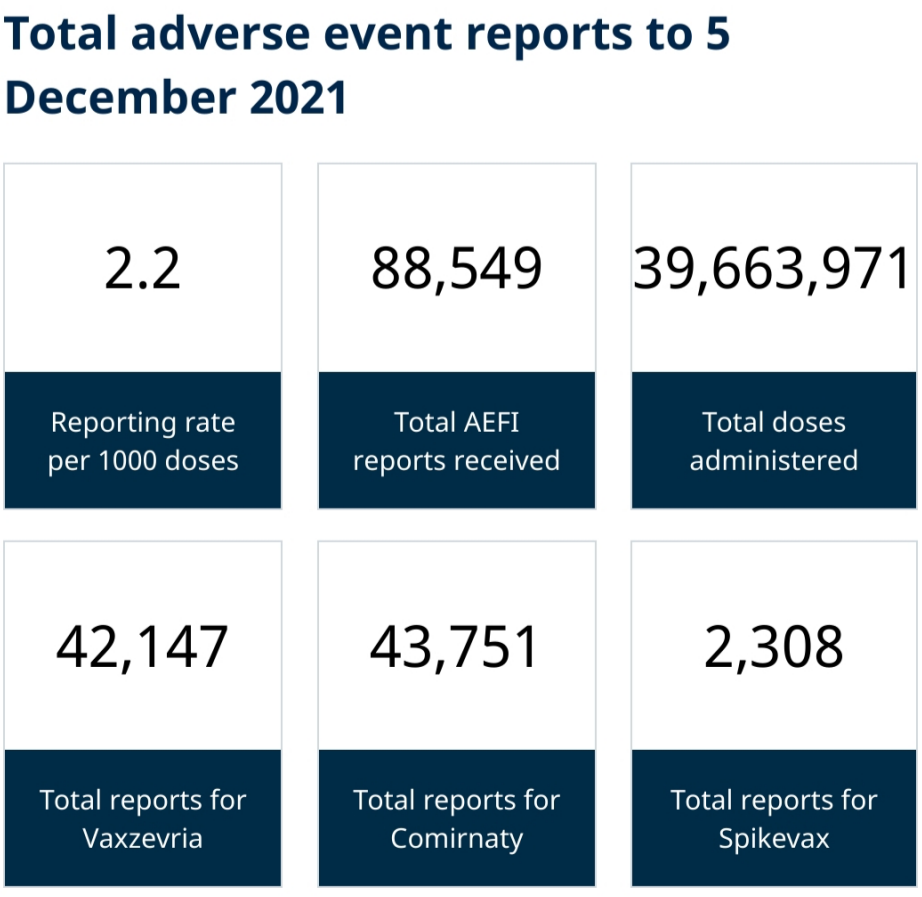
The AVN does here inform the Secretary that there are adverse events being identified in relation to each of the registrations and that the basis for your reaching a state of satisfaction with respect to the safety and efficacy of the registrations is liable for review.

In this context, the AVN draws to your attention the following information regarding same:

a. The TGA database of Adverse Event Notifications for the Registrations extracted on 15 December 2021 for the period between 1 January 2021 and 1 December 2021 which disclose 663 deaths reported as an outcome of those Registrations and a total of 89,026 adverse event notifications: https://apps.tga.gov.au/PROD/DAEN/daen-entry.aspx

b. The TGA COVID-19 vaccine weekly safety report released 9 December 2021, which acknowledges 700 reported Deaths from the vaccines, where the TGA alleges only 11 of these reported Deaths were linked to the vaccines, and where the below reporting figures have resulted from the vaccines:

https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-09-12-2021



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c. World Health Organisation Global Advisory Committee on Vaccine Safety (GACVS): updated statement regarding myocarditis and pericarditis reported with COVID-19 mRNA vaccines report dated 27 October 2021 that notes that Scandinavian countries have suspended or made recommendations respectively regarding the use of the Pfizer Registration and the Moderna Registration:
https://www.who.int/news/item/27-10-2021-gacvs-statement-myocarditis-pericarditis-covid-19-mrna-vaccines-updated

d. Subramanian, S.V., Kumar, A. ***Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States***. Eur J Epidemiol (2021). https://doi.org/10.1007/s10654-021-00808-7

e. Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19 (as of 29 January 2021), evidencing use of the Proportional Reporting Ratio for adverse event safety signal analysis: www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf .

f. Mclachlan S, et al, ***Analysis of COVID-19 vaccine death reports from the Vaccine Adverse Events Reporting System (VAERS) Database Interim: Results and Analysis***. ResearchGate (June, 2021):
www.researchgate.net/publication/352837543_Analysis_of_COVID-19_vaccine_death_reports_from_the_Vaccine_Adverse_Events_Reporting_System_VAERS_Database_Interim_Results_and_Analysis

g. Julia Schneider et al ***Postmortem investigation of fatalities following vaccination with COVID-19 vaccines:***
https://pubmed.ncbi.nlm.nih.gov/34591186/

h. Diaz J, et al, ***Myocarditis and Pericarditis After Vaccination for COVID-19***:
https://jamanetwork.com/journals/jama/fullarticle/2782900

i. Andeweg S. et al, ***Increased risk of infection with SARS-CoV-2 Beta, Gamma, and Delta variant compared to Alpha variant in vaccinated individuals:***
www.medrxiv.org/content/10.1101/2021.11.24.21266735v1

j. Nordström P, et al, ***Effectiveness of Covid-19 Vaccination Against Risk of Symptomatic Infection, Hospitalization, and Death Up to 9 Months: A Swedish Total-Population Cohort Study***:
https://ssrn.com/abstract=3949410

k. Steven Gundry, ***Mrna COVID Vaccines Dramatically Increase Endothelial Inflammatory Markers and ACS Risk as Measured by the PULS Cardiac Test: a Warning***:
www.ahajournals.org/doi/10.1161/circ.144.suppl_1.10712

l. Günter Kampf, ***The epidemiological relevance of the COVID-19-vaccinated population is increasing***:
www.sciencedirect.com/science/article/pii/S2666776221002581

m. Shitrit P, et al, ***Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021***:
www.eurosurveillance.org/content/10.2807/1560-

7917.ES.2021.26.39.2100822#html_fulltext

n. Israel A, et al, ***Large-scale study of antibody titer decay following BNT162b2 mRNA vaccine or SARS-CoV-2 infection***:
https://pubmed.ncbi.nlm.nih.gov/34462761/

o. Chau N, et al, ***Transmission of SARS-CoV-2 Delta Variant Among Vaccinated Healthcare Workers, Vietnam***:
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3897733

p. Föhse F, et al ***The BNT162b2 mRNA vaccine against SARS-CoV-2 reprograms both adaptive and innate immune responses***:
www.medrxiv.org/content/10.1101/2021.05.03.21256520v1.full

q. Servellita V, et al, ***Predominance of antibody-resistant SARS-CoV-2 variants in vaccine breakthrough cases from the San Francisco Bay Area, California***:
www.medrxiv.org/content/10.1101/2021.08.19.21262139v1.full

r. S Subramanian and Akhil Kumar, ***Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States***:
https://link.springer.com/article/10.1007/s10654-021-00808-7

s. Cohn B, et al, ***Breakthrough SARS-CoV-2 infections in 620,000 U.S. Veterans, February 1, 2021 to August 13, 2021***:
www.medrxiv.org/content/10.1101/2021.10.13.21264966v1

t. Gazit, S, et al, ***Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections***:
www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.full

u. Singanayagam, A, et al, ***Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study***:
www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00648-4/fulltext

v. Jack Davis, ***Sweden Suspends Moderna Shot Indefinitely After Vaxxed Patients Develop Crippling Heart Condition***:
www.westernjournal.com/sweden-suspends-moderna-shot-indefinitely-vaxxed-patients-develop-crippling-heart-condition/

w. Nordström, Peter and Ballin, Marcel and Nordström, Anna, ***Effectiveness of Covid-19 Vaccination Against Risk of Symptomatic Infection, Hospitalization, and Death Up to 9 Months: A Swedish Total-Population Cohort Study***: https://ssrn.com/abstract=3949410

x. The Vaccine Adverse Event Reporting System located at:
https://vaers.hhs.gov/data/datasets.html.

y. The OpenVAERS Adverse Event reporting system created using VAERS data for Covid-19 vaccines only:
https://openvaers.com/

z. A presentation of publicly available US VAERS raw data, reformatted into charts and histograms found here:
https://youtu.be/aPFweiO44xo

aa. EbMC CiC & The Evidence-Based Medicine Consultancy Ltd, ***Updated Report of UK Yellow Card data for COVID-19 vaccines up to 30th June 2021***, submitted to to Dr. June Raine, the Chief Executive of the Medicines and Healthcare products Regulatory Agency (MHRA), on 9th June 2021:
https://ebmcsquared.org/wp-content/uploads/2021/08/UpdatedReportYellowCardData_20210809.pdf

After extensive consultation with eminent physicians and scientists, several of whom have recognised credentials with respect to the post-marketing safety surveillance regulatory obligations required in respect of vaccines; and after extensive consideration of the above cited materials and data sources, (together with many more peer reviewed papers and expert analysis of publicly available data the AVN can further submit for the benefit of the Secretary), the AVN has concluded the above Covid-19 vaccines:

- Are seriously unsafe, and
- There exists a significant causal connection between adverse events (including death) and the Registrations.

The AVN requires that you respond to this correspondence confirming that you will:

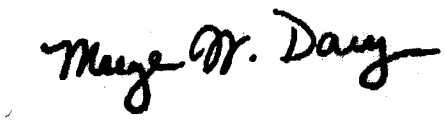
a. expressly consider suspending or cancelling the Registrations;
b. that you will suspend the provisional approval of the Pfizer Registration insofar as it relates to persons under the age of eleven (11) pending further investigation; and
c. that you will provide, publicly and to our office, reasons for your decisions relating to the above.

Absent a response to this correspondence by no later than 3:00pm on Friday, 24 December 2021, the AVN will have no choice other than to seek the Court's intervention.

The AVN confirm that this correspondence is written on an expressly open basis and may be produced to the Court if necessary.

We look forward to your response.

Yours faithfully,



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