People for Safe Vaccines Ltd
ABN 34 646 047 647
Unit 805, Level 8
220 Collins St
Melbourne 3000
www.peopleforsafevaccines.org

8 December 2021

The Hon. Greg Hunt
Minster of Health
Department of Health
Canberra ACT 2600
By email: Minister.Hunt@health.gov.au

Dear Minister,

Pfizer Covid-19 Vaccine
Post-Market Safety Data Disclosure

1. We are a not-for-profit with the object of promoting vaccine safety and efficacy, with a membership of over 3,000 concerned Australians.

2. As you are aware, the Pfizer Covid-19 vaccine trade name Comirnaty is provisionally approved by the Therapeutic Goods Administration (**TGA**) for use in Australia for persons aged 5 years and above. The Pfizer vaccine was first administered in Australia on 22 February 2021, the start date of the government's rollout plan.

3. Various other countries commenced their Covid-19 vaccine rollouts using the Pfizer vaccine prior to Australia. The United States commenced its rollout under Emergency Use Authorisation on 16 December 2020.

4. In response to a Freedom of Information Act application, a recent U.S. Federal Court ruling directed the Food and Drug Administration to release documents submitted by Pfizer Inc in relation to the safety monitoring of their Covid-19 vaccine. The first release disclosed a post-market safety monitoring report covering various countries between 1 December 2020 and 28 February 2021, entitled "*5.3.6 cumulative analysis of post-authorization adverse event reports of pf-07302048 (bnt162b2) received through 28-feb-2021*" (**Pfizer report**)[1], which reveals the following.

[1] https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf

- Cumulatively, through 28 February 2021, there was a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. (p.6)
- There were 1,223 fatal cases, 11,361 not recovered at time of report, 520 recovered with sequelae and 9,400 unknown. (p.7)
- In 46 cases reported age was <16-year-old and in 34 cases <12-year-old. (p.7)
- The classes that contained the greatest number of events, in the overall dataset, were General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693). (pp.7-8)
- There were a total 93,473 events covering lymphadenopathy, tachycardia, nausea, diarrhoea, vomiting, pyrexia, fatigue, chills, injection site pain, pain, malaise, asthenia, site erythema and swelling, influenza-like illness, Covid-19, injury, poisoning and procedural complications, myalgia, pain in extremity, arthralgia, headache, dizziness, paraesthesia, hypoesthesia, dyspnoea, cough, oropharyngeal pain, pruritis, rash, erythema, hyperhidrosis and urticaria. (pp.8-9)
- Identified risks include anaphylaxis, vaccine associated enhanced disease and vaccine associated enhanced respiratory disease. (pp.9-10)
- There were 1,833 total cases of anaphylaxis, or which 290 were confirmed to the highest level of certainty. (p.10)
- There were 1,403 cardiovascular cases (3.3% of the total monitored dataset), of which 241 are medically confirmed and 1162 are non-medically confirmed, with 136 fatalities from 946 serious cases, including Tachycardia (1098), Arrhythmia (102), Myocardial infarction (89), Cardiac failure (80), Acute myocardial infarction (41), Cardiac failure acute (11), Cardiogenic shock and Postural orthostatic tachycardia syndrome (7 each) and Coronary artery disease (6). (pp.16-17)
- Missing information was identified for Use in pregnancy and lactation, Use in paediatric individuals <12 years of age, and Vaccine effectiveness (pp.12-15).
- Pregnancy outcomes for 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). (p.12)
- Vaccination was ineffective in 1,665 cases (3.9 % of the total dataset) of which 1,100 were medically confirmed and 565 non medically confirmed. (p.14)
- Covid-19 was reported in 3,067 cases (7.3% of the total PM dataset), of which 1013 are medically confirmed and 2054 are non-medically confirmed; (p.17)
- Haematological events were reported in 932 cases (2.2 % of the total dataset), of which 524 were medically confirmed and 408 non-medically confirmed. (p.18)
- Autoimmune events were reported in 1,050 cases (2.5 % of the total dataset), of which 760 were medically confirmed and 290 non-medically confirmed. (p.20)

- Musculoskeletal events were reported in 3,600 cases (8.5% of the total dataset), of which 2045 were medically confirmed and 1,555 non-medically confirmed. (p.20)
- Other events reported included hepatic, facial paralysis, neurological, multiple organ disfunction, renal, thromboembolic, stroke and vasculitis. (pp.18-25)
- There were 7 fatal medication error outcomes. (p.26).

5. On any reasonable analysis, the Pfizer report discloses a wide variety of serious safety and efficacy concerns with the vaccine. Compare these with the safety profile of Covid-19 itself:

    - Covid-19 is practically indistinguishable from any other strain of common cold, seasonal flu or flu-like illness.[2]
    - 80 percent of cases experience mild or no symptoms and recover without medication within 14 days.[3]
    - Mortality risk is overwhelmingly in the very elderly and those with serious comorbidities.[4]
    - Survival rates are above 99 percent overall and much higher for those who are not already very ill or frail.[5]

6. A search of the TGA's Database of Adverse Event Notifications as at today's date reveals some 42,337 adverse reports in connection with the Pfizer product, including 242 deaths.[6] Consistent with the Pfizer report, serious events are occurring across all areas of human biology including cardiac, respiratory, nervous system, blood and lymph, gastrointestinal, skin, musculoskeletal and tissue, reproductive, vascular, psychiatric, neurologic and eyesight.

7. As at 22 February 2021, the government reported 28,930 total cases and 909 deaths related to Covid-19.[7] Presently, the government reports some 220,508 cases and 2,065 deaths.[8] Plainly, the Covid-19 vaccine program, if it was intended to improve the health of Australians, has been an abject failure.

8. Under the circumstances, the following questions arise:

    (a) When did the Minister or his administration become aware of the Pfizer report?

---

[2] Covid-19 is diagnosed by resort to PCR, a technique that detects fragments of nucleic acids allegedly from a virus for which no complete and intact genomic sequence exists outside of a computer program.
[3] Department of Health, *CDNA National Guidelines for Public Health Units*, v.6.1 (15 November 2021), p.10
[4] https://www.abs.gov.au/articles/covid-19-mortality-1
[5] https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/coronavirus-covid-19-case-numbers-and-statistics
[6] https://apps.tga.gov.au/PROD/DAEN/daen-report.aspx
[7] https://www.health.gov.au/sites/default/files/documents/2021/02/coronavirus-covid-19-at-a-glance-22-february-2021_0.pdf
[8] https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/coronavirus-covid-19-case-numbers-and-statistics

(b) What adverse event reports were obtained by your administration prior to rollout of the Pfizer vaccine in Australia?

(c) What steps does the Minister intend to take under the circumstances? Specifically, will he order an immediate suspension and recall of the Pfizer vaccine pending a thorough independent safety audit?

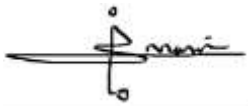
(d) What is the government's policy in relation to suspension/ recall – specifically, how many need to get very ill or die from the vaccine?

(e) If the Minister was not made aware of the safety issues with the Pfizer product by the first phase of rollout, will the Minister now provide details of the business units and identities of agency officers responsible for briefing the Minister on the safety aspects of the Pfizer vaccine for the purposes of possible legal proceedings?

9. We look forward to the Minister taking appropriate action as a matter of urgency to protect the lives of Australians, and to his response within 14 days outlining that course of action.

Yours sincerely,
People for Safe Vaccines





Serene Teffaha	Dr Judy Wilyman	Mani Shishineh
Chief Executive Officer	Director	Director