CLEMENSHASKIN
LEGAL

Suite 261, 585 Little Collins St
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Australia

5 November 2020

Secretary
Department of Health
GPO Box 9848
Canberra ACT 2601

By email: enquiries@health.gov.au

Dear Dr Murphy,

Provisional Determination – AstraZeneca Pty Ltd
Provisional Determination – Pfizer Australia Pty Ltd
Request for Statement of Reasons

I act on behalf of persons aggrieved by the above provisional determinations for development of COVID-19 vaccines made under the s.22D(2) of the *Therapeutic Goods Act 1989* ("TG Act") granted 9 and 14 October 2020 respectively (together "the decisions").

1. My clients include a growing number of people and associations from the health and law enforcement sectors and the wider community, namely doctors, nurses, police, vaccine-injured and others who are uniting in grave concern as to the potential impact of the decisions upon them, their families, those in their care and the Australian public, due to an apprehended fear of harm in relation to these vaccines.

2. We note the Government's efforts in expediting the development of safe and effective COVID-19 vaccines, which have included:
   - various announcements from the Prime Minister;
   - a publication entitled Australia's COVID-19 Vaccine Treatment and Strategy;
   - formation of a COVID-19 Vaccines and Treatments for Australia – Science and Industry Technical Advisory Group;
   - conditional procurement of over 50 million doses of vaccine.

3. The provisional determination pathway under the TG Act as detailed at the Department of Health website alleviates the drug company sponsor of significant obligations prior to listing the vaccine for sale and supply in Australia. You advert to this in the text of the AstraZeneca Pty Ltd decision:

   Normally for a vaccine to be registered in Australia, a sponsor (usually a pharmaceutical company) is required to submit a complete and comprehensive package of data to the TGA. A formal evaluation is then carried out in multiple stages by technical experts, prior to a decision being made.

4. Unlike the normal approval process for new medicines, under the provisional determination pathway, the sponsor need only submit evidence of a clinical plan to submit comprehensive data on safety and efficacy within 6 years of listing (TG Regulations 1990, reg.10L(d)). In light of the departure from the normal process which would subject a new vaccine to extensive regulatory oversight evaluation and scrutiny prior to market, there are natural and legitimate widespread concerns as to the safety and efficacy of any COVID-19 'fast track' vaccine and the enthusiasm with which a minimally-tested and potentially harmful product is being promoted.

5. Moreover, health industry workers are likely to be responsible for administering immunisations. These workers are entitled to know whether they can comply with their professional and ethical duties when treating patients, clients and consumers diagnosed with COVID-19 by means of vaccination. Otherwise, they may be exposed to substantial personal injury claims and their own consciences severely impacted in the event the people who depend on them for care suffer harm.

6. Accordingly, with reference to s.13(1) of the *Administrative Decisions (Judicial Review) Act 1977*, on behalf of my clients, being persons whose interests are or would be affected by the decisions, I hereby request that you furnish a statements in writing setting out the findings on material questions of fact, referring to the evidence or other material on which those findings were based and giving the reasons for each of the decisions.

7. I look forward to receiving the Statements of Reasons within 28 days of the date of this letter.

Yours sincerely
CLEMENS HASKIN LEGAL
Per:

Benedict S. Clemens
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