Australian Government
Department of Health
Therapeutic Goods Administration

Benedict S Clemens
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Our Reference: E20-357452/E20-360541

Dear Mr Clemens

Request for statement of reasons – Provisional determinations concerning AstraZeneca Pty Ltd and Pfizer Australia Pty Ltd COVID-19 vaccine candidates

I refer to your letter dated 5 November 2020, in which you requested a statement of reasons under section 13 of the *Administrative Decisions (Judicial Review) Act 1977* (**ADJR Act**), concerning two recent provisional determinations made by me as a delegate of the Secretary of the Australian Government Department of Health (**the Decisions**).

You have made the request on behalf of your clients to whom you have referred as including 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 have concerns regarding the potential impact of the Decisions.

The purpose of this letter is to advise in accordance with subsection 13(3) of the ADJR Act that I am not satisfied that your clients (who have not been expressly identified) are entitled to request a statement of reasons under section 13 of the ADJR Act. Nevertheless, I recognise the importance of transparency in government decision-making, particularly in matters relating to significant public health concerns such as the COVID-19 pandemic.

Accordingly, I provide the following information regarding the Decisions. This information is not a statement of reasons under section 13 of the ADJR Act. However, it is intended to provide you and your clients with a reasonable explanation as to my decisions to grant the provisional determinations in the circumstances.

Consistent with the Department's position in relation to the handling of confidential commercial information, I have not included any information in this letter that was supplied in-confidence to the Department or would reveal a trade secret. Incidentally, such information would not be required to be given in a statement of reasons.

As you know, the Decisions were made following applications for provisional determination from AstraZeneca Pty Ltd (**AstraZeneca**) and Pfizer Australia Pty Ltd (**Pfizer**) in relation to their respective COVID-19 vaccine candidates.

What is a provisional determination?

A provisional determination is a decision that determines that a person is eligible to make an application to the Secretary to have a medicine evaluated for provisional registration on the Australian Register of Therapeutic Goods (**Register**).

Ordinarily, an applicant is required to submit a complete and comprehensive data package to the Therapeutic Goods Administration (**TGA**), a part of the Department, for the purpose of making an application for registration. The provisional pathway provides a formal and transparent mechanism for expediting the registration of a promising new medicine where that medicine would represent a significant advance on currently available methods for preventing, diagnosing and treating life-threatening or seriously debilitating conditions.

Under the provisional pathway, a delegate of the Secretary first determines whether a provisional determination may be granted to enable an application for provisional registration to be made. The decision on provisional determination is facilitative in nature (relating to an application pathway) and by no means is indicative of the ultimate decision that may be made on any subsequent application for provisional registration itself.

The effect of the provisional determination is that an application for provisional registration may be submitted to the TGA for consideration. In considering an application for provisional registration, a delegate must be satisfied that the safety and efficacy of the medicine have been satisfactorily established from preliminary data. For more information, see the TGA's website guidance materials concerning provisional determinations.

When can a provisional determination be made?

Under section 22D of the *Therapeutic Goods Act 1989* (**the Act**) and regulations 10K and 10L of the *Therapeutic Goods Regulations 1990* (**the Regulations**), a provisional determination can be made if all of the following criteria are met:

(a) the medicine is a new prescription medicine;

(b) an indication (a specific therapeutic use) of the medicine is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition;

(c) no therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register other than provisionally registered medicines;

(d) there is preliminary clinical data demonstrating that the medicine is likely to provide a major therapeutic advance; and

(e) the person who made the application […] has provided sufficient evidence of the person's plan to submit comprehensive clinical data on the safety and efficacy of the medicine before the end of the six years that would start on the day that provisional registration of the medicine would commence if the Secretary were to provisionally register the medicine.

Why were provisional determinations concerning the AstraZeneca and Pfizer vaccines made?

As delegate of the Secretary, I considered the applications from AstraZeneca and Pfizer against the criteria set out above. I determined that both vaccines satisfied the criteria in regulations 10K and 10L of the Regulations for the following reasons:

- the vaccines both contain active ingredients that have not been previously included in an entry in the Register, consistent with the definition of new prescription medicine as defined in regulation 2 of the Regulations as follows:

  new prescription medicine means a prescription medicine that contains:

  (a) a chemical, biological or radiopharmaceutical active ingredient that has not previously been included in an entry in the Register; or

(b) a fixed combination of chemical, biological or radiopharmaceutical active ingredients at least one of which has not previously been included in an entry in the Register;

- the vaccines are indicated for the prevention of COVID-19, which is a life-threatening medical condition;
- there are no therapeutic goods included in the Register for the prevention of COVID-19 at this time;
- COVID-19 is a highly infectious and, in some cases, fatal disease that is currently causing a global pandemic. Given that there is not currently a registered COVID-19 vaccine, and the seriousness of the health threat presented by that disease, a COVID-19 vaccine would provide a major therapeutic advance.
- AstraZeneca and Pfizer provided sufficient evidence of a plan to submit comprehensive clinical data on the safety and efficacy of the medicine before the end of the 6 years.

I considered the preliminary clinical data accompanying the applications for the provisional determinations, and concluded that in each case that there was sufficient information to grant the determinations and therefore enable applications to be made for provisional registration.

The effect of the Decisions is that AstraZeneca and Pfizer are able to submit applications for registration of the respective COVID-19 vaccine candidates under the provisional pathway. Importantly, the Decisions do not guarantee that the applications for provisional registration will be successful.

The TGA has published a new hub page on its website relating to candidate COVID-19 vaccines (please refer to www.tga.gov.au/covid-19-vaccines). The page provides a foundational base of information on the TGA's regulatory processes relating to the vaccines and will be updated regularly to ensure that the Australian public remains informed of the latest developments.

Importantly, the page has recently been updated to confirm that the TGA has now received three applications for provisional registration and is now formally assessing preliminary data.

Yours sincerely

Dr Jane Cook
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group

Dated 2 December 2020