FOI 2565: Response to TGA grounds of refusal

1. Internal Review Para 23. 'Request is too voluminous to process':

Rat ovarian and testicular histology reports are now vital to the ongoing tens of thousands of reports suggesting the pattern of an oestrogenic effect on reproductive tissues. While references to these existing reports (mentioned but not referenced in the pre-clinical reproductive studies I have cited in my FOI request) may be scattered through a voluminous document, it is both possible and necessary to extract them.

2. Internal Review Para 24. 'Work involved in processing request…would divert resources of the TGA':

Adversely affected women's reproductive health should be considered a high priority by the TGA, as it is in the community (A. Mahdawi column The Guardian September 2021.and is starting to be referred to in the lay press.)

3. Internal Review Para 28. Pharmaceutical company reports of gonad histology are 'presented in such a way that it would be impractical to simply extract the relevant pages from the study':

It is the responsibility of the sponsor presenting the preclinical toxicology data to present it in a coherent and systematic manner. It is similarly the responsibility of the regulator to require this standard of reporting and presentation. If preclinical rat gonad histology reports are sprinkled over several thousand pages in a manner that is unextractable and unretrievable as has been stated, this suggests a poor presentation of data by the sponsor and a low standard of data acceptance by the regulator.

4. Internal Review Para 29. Preclinical animal gonad histology reports were 'provided to the TGA in confidence':

Information relevant to Reproductive Health as indicated by tens of thousands of adverse reproductive health reports indicates that this information should no longer be kept confidential from requesting reproductive health clinicians or those who have received vaccinations or those consenting to receive vaccines.

5. Internal Review Para 30. Many redactions will be needed because the requested documents are 'unpublished studies contain information that is commercially sensitive':

It is not known or stated why gonad histology would be commercially sensitive. Gonad histology reports would not normally be inextricably intermingled with the vaccine processes not stated in the patents. Again I refer to a standard of data presentation which appears to lack appropriate, customary and navigable organization and systematization. Since the TGA has industry funding, industry charges may need to be increased to employ trained staff to deal with any obstruction of FOI requests due to poor data presentation methodology, as has been indicated to be the problem by the internal reviewer.

6. Internal Review Para 31: 'both [pharmaceutical companies] have taken active steps to ensure the information contained within the documents is not disclosed to the general public':

It is of some concern that the sponsors whose products have been temporally associated with tens of thousands of adverse reproductive health event reports should have 'taken active steps to ensure

the information contained within the documents is not disclosed to the general public', and that despite the volume and significance of these adverse events, gonad histology is to remain a secret.

7. Internal Review paras 32-38: Too many hours of time would have to be devoted by scientists and lawyers to extract histology reports of ovaries and testes.

Histology reports of covid-19 vaccinated animal livers, spleens and adrenals have already been made accessible. Why would gonad organ histology reports require so much additional screening and collation by lawyers and scientists?

8. Internal Review para 39, 41, 43, 44, 45, and 46. 'Resources required to process your request [microscopy reports of animal gonads] outweigh the public interest in releasing the studies in their entirety':

Reproductive health adverse events of an oestrogenic nature have already been discussed in the BMJ on two occasions, in and in the Guardian newspaper. The public interest in reproductive health effects of these investigational vaccines (CIOMS definition) is appropriately very high and should remain so. It would undermine vaccine confidence should the TGA consider reproductive health of low priority.

9. Internal Review Para 47. 'there is already a number of publicly available resources that demonstrate the safety and efficacy of the Pfizer and AstraZeneca COVID-19 vaccines including in the context of male and female fertility and reproductive health':

None of the 9 resources listed, with which I am already familiar as a clinician and registered vaccine provider, present a microscopy report of vaccinated animal gonads following these provisionally registered products. I refer to the TGA's own statement: 'clinical data from clinical trials do not detect all possible adverse effects of a medicine because they usually do not continue for long enough to detect all possible adverse effects, they do not include enough patients ..they do not include all the different types of people who might eventually use the medicine'.(Evaluation of a new medicine- the TGA's lifecycle approach to regulation. TGA.)

10. Internal Review Para 48, 49, 53, 54. The TGA database of adverse event notifications contains weekly reports of adverse event notifications.

As a vaccine provider and a GP I am aware of the DAEN, and of VAERS and the UK yellow card reporting system, both of which were referred to in my FOI request, and of VIGIBASE and Eudra Vigilance and AusVaxSafety. The latter monitoring would not have the capacity to assess gonad disruptions over an interval of weeks or months. I have received no communication from the TGA or Dept of Health that would alert an Australian clinician to notify abnormal menses or postmenopausal bleeding to the DAEN post COVID-19 vaccinations. Therefore it unlikely such notifications would routinely be made.

11. Internal Review Paras 55, 56. The documents released in response to FOIs 2389 and 2183 do not contain all the information on those studies.

That is correct. However these documents do relate to and refer to the existence of gonad histology and verify that such reports do exist, as does the rat DART study (Pfizer) and the mouse DART studies (AZ vaccine).

12. Internal Review Para 58 states 'the public interest in evidence supporting the safety and efficacy of COVID-19 vaccines in Australia has already been met through the publication of the

supporting regulatory documents, in addition to the publicly available links referred to above, as well as through publication of information regarding adverse events on DAEN'.

During the recent RANZCOG webinar regarding COVID-19 vaccines in reproductive health care (September 29th) RANZCOG representatives and presenters stated they did not know why tens of thousands of women were experiencing new onset irregular menses and postmenopausal bleeding. The studies and links referred to have not investigated this matter whatsoever. Again I refer you to the column by Arwa Mahdawi article "Who says it's no big deal if the Covid vaccine temporarily disrupts menstrual cycles?" in the Guardian in September.

13. Internal Review paras 59-64 and 66. 'You did not agree to the TGA's suggested revised scope' of the FOI request:

My FOI request had already been revised to reduce the TGA workload. However, the appendices, annexures and particularly the raw data are required to view microscopy imaging etc. since complete gonad histology reporting is required to exclude an oestrogenic vaccine effect. I have left messages with the FOI Team as suggested in para 66 in mid September on the phone number supplied in the TGA correspondence and also on the phone number messages displayed on the website. As of October 21st 2021 these calls have not been returned. For microscopy of liver spleen and adrenals of BNT162b2 rats the appendices were referenced. Therefore It would seem consistent for microscopy of gonads to also be reported in appendices. I am unsure about annexures, which is why I phoned to discuss, as advised by the TGA correspondence.

Reasons for FOI Request

Complaint by xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx, reproductive health care clinician, regarding refusal of TGA to release information requested under FOI 2565 (your reference LEX25178) after revised scope of request and internal review.

The information requested is considered to be in the public interest.

Requested information: 'Histopathology (also known as histology or microscopy) reports of ovaries and testes of COVID-19 vaccinated animals who had received either BNT162b2 (Pfizer) or ChAdOx-1 (AstraZeneca) provisionally licensed for use in Australia.'

Six reasons for FOI request:

1. When this FOI Internal Review Request was lodged, over 30,000 women had reported new onset irregular menses and new onset post-menopausal bleeding to the Vaccine Adverse Event Reporting System in the USA and the Yellow Card reporting System in the UK. This safety concern has been discussed in the British Medical Journal (BMJ) on two separate occasions. New onset abnormal menses and post menopausal bleeding reports are now approaching 40,000. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) has stated that the College does not know why these adverse events are happening. The matter has raised public interest and led to patient enquiries at my clinic. It has been discussed in a column in the Guardian newspaper (Arwa Mahdawi article: "Who says it's no big deal if the Covid vaccine temporarily disrupts menstrual cycles?" September 2021)

2. The TGA 'Non-clinical Evaluation Report BNT162b2 [m-RNA] COVID-19 Vaccine (ComirnatyTM)' January 2021, FOI 2389 Document 6, Submission PM-2020-05461-1-2, states the concentration of

labelled mRNA vaccine nanoparticles in rat ovaries is measured at 10x the concentration of nanoparticles in other organs, with the exception of liver, spleen, adrenals and lymph. (This followed injection of rats with a 50 ucg dose of BNT162b2. Humans receive 2x30 ucg doses). Effect of vaccine nanoparticle concentration in the ovaries on ovarian histology is unknown.

3. Polyethylene sorbitan monooleate (polysorbate 80) present in AZ vaccine (amount not stated in PI) resembles the effect of diethylstilboestrol when injected into young rats and causes toxic effects on rat ovaries within 5 months. (M Gajdova et al. Delayed effects of neonatal exposure to Tween 80 on female reproductive organs in rats. 1993. 31 Food Chemical Toxicology 183). PS80 also caused abnormalities in rat uterine lining. This chemical is closely related to polyethylene glycol present in mRNA vaccine nanoparticles.

4. COVID-19 vaccines are being mandated for occupational sectors predominantly staffed by reproductive aged men and women. The concurrence of increasing, large numbers of similar patterned reproductive health adverse events with potential chemical aetiological adverse effects previously documented, warrants extraction of histological reports of ovaries and testes of vaccinated rats. It is imperative these histology reports are accessible for safety transparency and public vaccine confidence in safety transparency. Therefore the information requested under FOI is in the public interest.

5. Informed Consent requires access to all information that could be considered relevant to the health and wellbeing of the vaccine recipient. Therefore the information requested under FOI is in the public interest.

6. The success of the vaccine roll out programme may be enhanced by provision of the requested information, particularly for those who may be experiencing some hesitancy in this domain of their future health. Therefore the information requested under FOI is in the public interest.