Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D20-921987

Helena Smirnis
Email: sirendoll0@gmail.com

Dear Ms Smirnis

FREEDOM OF INFORMATION REQUEST FOI 1749
Notice of Decision

I refer to your request dated 27 May 2020 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

> *"One Independent Safety Study Test that the TGA relied upon, which was used to approve and register the HPV vaccine named Gardasil 9, where this one study/document was not funded by either a Pharmaceutical Company or any other Company with invested interests in this vaccine."*

Decision Maker

I am the Therapeutic Goods Administration (TGA) officer authorised to make this decision under section 23 of the FOI Act. What follows is my decision under the FOI Act.

Decision

I am notifying you of my decision under section 24A of the FOI Act to refuse your request for access as the documents you have requested do not exist.

Reasons for Decision

Section 24A of the FOI Act states that requests may be refused if all reasonable steps have been taken to find a document and the document does not exist. I am satisfied that all reasonable steps have been taken to find the documents requested and that the documents you have requested do not exist.

Your FOI request sought access to an independent safety study test that was relied upon by the TGA to approve and register Gardasil 9. The request indicated that the independent safety study test must be one that was not funded by a pharmaceutical company or a company with invested interests in the vaccine. The TGA assessed a number of safety studies in relation to the registration of Gardasil 9, however these studies were not independently funded. On this basis, the documents you seek do not exist.

By way of background, the assessment by the TGA of safety studies funded and submitted by a sponsor (generally a pharmaceutical company) with an invested interest in a medicine, is part of the ordinary submission and assessment process for new prescription medicines, including vaccines. Although an independent safety study funded by an entity other than the sponsor could be relevant to the TGA's assessment of the safety of a vaccine, in practice, due to the large number of vaccine applications made and also, the resources required to undertake such safety studies, independent entities with no financial interest in the vaccine may not have the capability or incentive to routinely undertake such studies. Accordingly it is generally the sponsor that funds and submits these studies. Irrespective of who funds the study, human studies should always involve

independent Ethics Approval for each study site, and adherence to the principles of International Good Clinical Practice and human experimentation in the Declaration of Helsinki.

Additionally, the TGA carefully assesses the results of all clinical trials submitted by the sponsor for all medicines, including those submitted for Gardasil 9. However, it is important to note that there may be studies conducted by the sponsor or another entity, which have not been submitted by the sponsor to the TGA for evaluation. These studies may or may not have been independently funded. The TGA also scrutinises the way in which trials are conducted. We require well-designed trials of a sufficient length with a sufficient number of people who represent the people for whom the vaccine is intended. The results must demonstrate that the benefits of the vaccine greatly outweigh the risks. The TGA's decision of whether to register a vaccine for use in Australia is informed by the advice of the Advisory Committee on Vaccines (ACV). The ACV is an independent committee appointed by the Australian Government Minister for Health. It is composed of members with expertise in science, medicine and public health. Further information on the approval process for vaccines is at www.tga.gov.au/vaccines-overview.

The Australian Public Assessment Report (AusPAR) outlines the studies that were submitted for the most recent approval of January 2017. This AusPAR is available on the TGA's website – www.tga.gov.au/auspar/auspar-human-papillomavirus-9-valent-vaccine. Please refer to the list of studies contained within the 'Safety – Studies providing safety data'. You may also wish to enter the relevant protocol number into an internet search engine to determine who conducted these studies.

Review and Complaint Rights

If you are not satisfied with this decision, you can either seek internal review or apply to the OAIC for review of the decision. Further information can be found on the OAIC website at the following link: www.oaic.gov.au/freedom-of-information/reviews-and-complaints/

If you have any queries regarding this matter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely

Electronically signed and authorised by

Adrian Bootes
Assistant Secretary
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
26 June 2020