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[redacted]

Ref: H201900011

Dear [redacted]

Response to your request for official information

I refer to your request of 2 January 2019 under the Official Information Act 1982 (the Act) for:

> *"I formally request, within the provisions provided in the Official Information Act 1982 (1982 No 156) copies of any independent tests, that were contracted out by the Ministry of Health, on Infanrix hex vaccines from batches that have been administered to recipients in New Zealand and that may remain in stock in New Zealand.*
> *These tests should include:*
> *1. Testing for the presence, in the vaccine solution of the following antigens: tetanus, diphtheria and pertussis toxoids; inactivated poliomyelitis viral strains 1-2-3; and hepatitis B surface antigen.*
> *2. Chemical contamination from the manufacturing process or cross-contamination with other manufacturing lines.*
> *3. Chemical toxins.*
> *4. Bacterial peptide toxins."*

Medsafe has not arranged for any independent testing of the Infanrix-hexa vaccine. I have therefore decided to refuse your request under section 18(e) of the Act as the information you have requested does not exist. As PHARMAC is responsible for the procurement of vaccines and holds contracts for the supply of funded vaccines, you may wish to contact them with your request.

While Medsafe does not conduct routine vaccine testing, the medicine consent process, Good Manufacturing Practice (GMP) requirements, and safety monitoring, provide a high level of confidence that medicines with consent to distribute in New Zealand are safe and effective, and of high quality. If Medsafe is concerned about the quality of a medicine, we can arrange for independent testing.

Medsafe continually monitors the safety of vaccines as with all medicines. Medsafe routinely uses information from many different sources to monitor vaccine safety including clinical and epidemiological studies, case reports, published literature, pharmaceutical companies and other regulatory authorities. Importantly, anyone can report suspected adverse reactions to vaccines to Medsafe. This includes reactions that are suspected to be due to a quality problem with the vaccine.

Please see the following link for further information on Medsafe's work to ensure vaccine efficacy, quality and safety:
https://medsafe.govt.nz/safety/WhereCanIFindInfoAboutVaccines.asp

You have the right, under section 28 of the Act, to ask the Ombudsman to review any of the decisions made relating to this request.

Yours sincerely

[redacted]

Deputy Director-General
Health System Improvement and Innovation