133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T +64 4 496 2000

31 July 2019

[redacted]

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act), transferred from the Office of Hon Dr David Clark to the Ministry of Health, on 26 June 2019 for:

> *"1. All independent trials including double blind placebo tests on all vaccines on the New Zealand Schedule particularly from the years 1986 and there after conducted by the ministry or for the ministry.*
> *2. Each trial to include the authors and ingredients of the placebo and data on reasons for those taking part in the trial to be excluded."*

On 27 June 2019, you refined your request to include:

> *"3. What the minimum lawful requirement for testing vaccines on our schedule from the Ministry of Health?*
> *4. For individuals who suspect they have been injured by a vaccine in New Zealand: how is it advertised and shown through the Ministry of Health the process for compensation .*
> *5. Given the most recent studies some listed below will you consider shelving HVP vaccines until we know more about the damage they are causing? Otherwise please provide all independent studies you have based the decision to continue on with this vaccine.*
> *6. What is the Ministry of Health plan now for taking round up or glysophate off the shelves now the this trial has been lost for the third time the the US showing Monsanto deliberately neglected to show the danger of this product causing cancer?"*

Information held by the Ministry pertaining to your request is outlined in Appendix 1 attached to this letter. I trust this information fulfils your request. You have the right, under section 28 of the Act, to ask the Ombudsman to review any decisions made under this request.

Please note this response (with your personal details removed) may be published on the Medsafe website.

Yours sincerely

Chris James
Group Manager
Medsafe

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T +64 4 496 2000

Appendix 1

Request	Response
1. All independent trials including double blind placebo tests on all vaccines on the New Zealand Schedule particularly from the years 1986 and there after conducted by the ministry or for the ministry.	The Ministry does not conduct or commission clinical trials for medicines (including vaccines) nor does it hold information on independent clinical trials that is not already publicly available. As you may be aware, clinical trials can be promoted and funded by a variety of sponsors, including pharmaceutical companies, research charities, foundations and medical organisations. These are defined as 'independent' when they are promoted by scientific organisations (academic or non-profit) and funded by public or charitable money, research centres, or voluntary groups. These parts of your request are therefore refused under section 18(g) of the Act, as the information requested is not held by the Ministry and is not believed to be held by another agency subject to the Act.
2. Each trial to include the authors and ingredients of the placebo and data on reasons for those taking part in the trial to be excluded.	
3. What the minimum lawful requirement for testing vaccines on our schedule from the Ministry of Health?	Under section 30 of the Medicines Act, approval from the Director-General of Health is required before a clinical trial using a new medicine may commence in New Zealand. The approval process for clinical trials is administered by Medsafe. You can find a copy of the Guideline on the Regulation of Therapeutic Products in New Zealand (the Guideline) on the Medsafe website: https://medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part11.pdf The requirements to obtain approval of a medicine are also explained in part two of the Guideline. The schedule is constructed from approved vaccines through the PHARMAC tendering process.
4. For individuals who suspect they have been injured by a vaccine in New Zealand: how is it advertised and shown through the Ministry of Health the process for compensation	In New Zealand, there is no separate administrative entity to address vaccine injuries. Instead, these are covered by the broad Accident Compensation Corporation (ACC), which is a statutory corporation that provides no-fault compensation for any personal injury and death caused by accident. This is the same for any injury caused by a medicine. Medsafe is responsible for regulating medicines and monitoring available information to ensure that approved vaccines remain acceptably safe for use. Healthcare professionals and consumers are encouraged to report adverse events following immunisation to the Centre for Adverse Reactions Monitoring (CARM), which is part of the New Zealand Pharmacovigilance Centre. Pharmaceutical companies also submit adverse event reports. You can find reports presented to the Medicines Adverse Reactions Committee on the Medsafe website: https://medsafe.govt.nz/committees/MARC/Reports.asp
5. Given the most recent studies some listed below will you consider shelving HVP vaccines until we know more about the damage they are causing? Otherwise	As you may be aware, there are over 150 different types of human papillomavirus (HPV). Around 40 HPV types can infect the population.

Request	Response
please provide all independent studies you have based the decision to continue on with this vaccine.	Currently, there are three HPV vaccines approved for use in New Zealand: • Cervarix • Gardasil • Gardasil 9 Clinical trials showed that women who received HPV vaccine (Gardasil or Gardasil 9) were less likely to have abnormal smear tests (or develop precancerous cells in the cervix) than those who had not been vaccinated. Further information on HPV vaccines (including efficacy and safety) can be found on the Medsafe website: https://medsafe.govt.nz/Consumers/educational-material/gardasil9QandA.asp#safe I have also included some additional information that may be useful to you: • Data Sheets and Consumer Medicine Information https://medsafe.govt.nz/Medicines/infoSearch.asp • Safety reviews presented to and discussed by the Medicines Adverse Reactions Committee https://medsafe.govt.nz/profs/MARC/Minutes.asp • Previous OIA responses https://medsafe.govt.nz/publications/oia.asp
6. What is the Ministry of Health plan now for taking round up or glysophate off the shelves now the this trial has been lost for the third time the the US showing Monsanto deliberately neglected to show the danger of this product causing cancer?	The Ministry of Primary Industries (MPI) monitors and controls the use of glyphosate (https://mpi.govt.nz/food-safety/food-safety-for-consumers/whats-in-our-food-2/chemicals-and-food/agricultural-compounds-and-residues/glyphosate/) while the Environmental Protection Agency (EPA) regulates the manufacture, importing, use, storage, and transportation of hazardous substances, (such as glyphosate) for environmental, and health and safety purposes. The information you have requested is not held by the Ministry, however, you may wish to contact MPI or the EPA • MPI: official.informationact@mpi.govt.nz • EPA: ministerials@epa.govt.nz