MINISTRY OF HEALTH
MANATŪ HAUORA

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23 SEP 2019

[redacted]

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 26 August 2019 for:

> *"1. From your reply: "Before any vaccine is approved for use in New Zealand its safety, quality and efficacy is independently assessed by the medicines regulator MedSafe". Please confirm that the MedSafe assessment, you refer to consists of a review of literature supplied by the vaccine manufacturer and the assessment does not include any independent testing of the vaccine as stated by Keriana Brooking, Deputy Director-General, Health System Improvement and Innovation, Ministry of Health, in response to an Official Information Act Request "Medsafe does not conduct routine vaccine testing".*
> *2. The following question was included in the 7/8/19 email to you: "Some vaccines include other ingredients to make them more effective." "They are not harmful in the quantities used."*
> *You responded with this statement: "To construct the immunisation schedule the combined effects of vaccines is also considered" Please explain the process that was undertaken prior to the July 2017 vaccine schedule changes that considering the effects of combining the new vaccines with the vaccines administered prior to the change . Please include a reference(s) to the clinical trial(s) done prior to starting the July 2017 vaccine schedule that was performed on infants aged from 6 weeks old to 15 months old that monitored the effects of the new vaccine combination.*
> *3. Please include in your response a reference to the independent laboratory test report (see page 1; paragraph 6) for the current batch of MMR II vaccine that includes a complete analysis of all parts of the vaccine including ingredients and contaminants."*

It is correct that Medsafe's assessment of the safety, efficacy and quality of vaccines is based on a review of documentation provided by the manufacturer. Medsafe does not conduct its own independent routine testing as part of the assessment of applications for the registration of new vaccines.

Regarding question two of your request, the 2017 National Immunisation Schedule changes only include vaccines that were already on the schedule and/or were approved and funded for use in New Zealand. These vaccines were either for the Childhood Immunisation programme or the high-risk immunisation programme (i.e. vaccines funded for individuals

with an increased risk of a vaccine preventable disease due to other medical conditions). The changes involved were associated with brand changes and eligibility to the funded vaccine. No new vaccines were added to the National Immunisation Schedule and all vaccines affected by the 2017 Immunisation schedule were in use or previously used on the schedule. These vaccines have been successfully used within New Zealand for several years.

Question three of your request is refused under 18(g) of the Act, as this information is not held by the Ministry and is not believed to be held by another agency subject to the Act.

I trust that this information fulfils your request. Under section 28 of the Act, you have the right to ask the Ombudsman to review any decisions made under this request.

Please note that this response (with your personal details removed) may be published on the Ministry of Health website.

Yours sincerely

D Woodley

Deborah Woodley
Deputy Director-General
Population Health and Prevention