

02 SEP 2019

Tracy Livingston

By email: [fyi-request-10897-8b223f56@requests.fyi.org.nz](mailto:fyi-request-10897-8b223f56@requests.fyi.org.nz)

Ref: H201907090

Dear Tracy

### Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) for information held by the Ministry of Health (the Ministry) on Sudden Infant Death Syndrome (SIDS) and Centre for Adverse Reactions Monitoring (CARM) fatality reports. A copy of your full request, including the Ministry's response to each question is itemised in Appendix 1 of 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 Ministry website.

Yours sincerely



Chris James  
**Group Manager**  
**Medsafe**

## Appendix 1

| #    | Requested information  | Response  |                    |        |                              |                    |      |    |     |     |      |    |     |     |      |    |     |     |      |    |     |    |      |    |     |     |
|------|--|---|--------------------|--------|------------------------------|--------------------|------|----|-----|-----|------|----|-----|-----|------|----|-----|-----|------|----|-----|----|------|----|-----|-----|
| 1a   | <i>What are the vaccination status of all of the SIDS/SUDI cases in the past five years?</i>           | <p>The table below shows the count of all SUDI deaths between 2012 to 2016. Please note that 2016 is the most recent year for which this data is currently available. Finalising mortality data takes several years as there are a variety of data quality processes involved before this information is published. Generally, provisional data becomes available around two years after the end of the year.</p> <p><b>Table 1. SUDI deaths between 2012 and 2016</b></p> <table border="1"> <thead> <tr> <th>Year</th> <th>Deaths</th> <th>Expected Vaccination Events*</th> <th>Vaccination Events</th> </tr> </thead> <tbody> <tr> <td>2012</td> <td>37</td> <td>157</td> <td>107</td> </tr> <tr> <td>2013</td> <td>41</td> <td>180</td> <td>147</td> </tr> <tr> <td>2014</td> <td>45</td> <td>181</td> <td>155</td> </tr> <tr> <td>2015</td> <td>44</td> <td>130</td> <td>81</td> </tr> <tr> <td>2016</td> <td>42</td> <td>177</td> <td>123</td> </tr> </tbody> </table> <p>The 'Expected Vaccination Events' and 'Vaccination Events' columns refer to the number of vaccinations a child is expected to have had (given their age at death), and the number of events they did have, respectively.</p> <p>*The expected number of events is derived from the immunisation schedule found at the following link: <a href="https://health.govt.nz/our-work/preventative-health-wellness/immunisation/new-zealand-immunisation-schedule">https://health.govt.nz/our-work/preventative-health-wellness/immunisation/new-zealand-immunisation-schedule</a>.</p> | Year               | Deaths | Expected Vaccination Events* | Vaccination Events | 2012 | 37 | 157 | 107 | 2013 | 41 | 180 | 147 | 2014 | 45 | 181 | 155 | 2015 | 44 | 130 | 81 | 2016 | 42 | 177 | 123 |
| Year | Deaths   | Expected Vaccination Events*  | Vaccination Events |        |                              |                    |      |    |     |     |      |    |     |     |      |    |     |     |      |    |     |    |      |    |     |     |
| 2012 | 37   | 157   | 107                |        |                              |                    |      |    |     |     |      |    |     |     |      |    |     |     |      |    |     |    |      |    |     |     |
| 2013 | 41   | 180   | 147                |        |                              |                    |      |    |     |     |      |    |     |     |      |    |     |     |      |    |     |    |      |    |     |     |
| 2014 | 45   | 181   | 155                |        |                              |                    |      |    |     |     |      |    |     |     |      |    |     |     |      |    |     |    |      |    |     |     |
| 2015 | 44   | 130   | 81                 |        |                              |                    |      |    |     |     |      |    |     |     |      |    |     |     |      |    |     |    |      |    |     |     |
| 2016 | 42   | 177   | 123                |        |                              |                    |      |    |     |     |      |    |     |     |      |    |     |     |      |    |     |    |      |    |     |     |
| 1b   | <i>How many of these babies had also been given antibiotics? (at any age, not just when they died)</i> | <p>The Ministry cannot state the number of babies that have been given antibiotics or paracetamol, as this is not information we routinely collect or report on. These parts of your request are therefore refused under section 18(e) of the Act, as the requested information does not exist. For your information, the Ministry only holds PHARMAC-subsidised dispensings from community pharmacies. However, it is important to note that this does not include pharmaceuticals given directly by clinicians, or those bought over the counter.</p>   |                    |        |                              |                    |      |    |     |     |      |    |     |     |      |    |     |     |      |    |     |    |      |    |     |     |
| 1c   | <i>How many of these babies had also been given paracetamol (at any age, not just when they died)</i>  |   |                    |        |                              |                    |      |    |     |     |      |    |     |     |      |    |     |     |      |    |     |    |      |    |     |     |
| 2    | <i>In light of this causative link between SIDS and vaccination, has the</i>                           | <p>There is no causative link between vaccination (immunisation) and SUDI. For your reference, the article '<i>Sudden Unexpected Death in Infants (SUDI): No Causal Link to Vaccination</i>' is</p>   |                    |        |                              |                    |      |    |     |     |      |    |     |     |      |    |     |     |      |    |     |    |      |    |     |     |

| #     | Requested information  | Response   |      |             |             |       |             |   |       |                 |   |       |                    |   |       |  |    |       |  |    |       |                |    |
|-------|--|--|------|-------------|-------------|-------|-------------|---|-------|-----------------|---|-------|--------------------|---|-------|--|----|-------|--|----|-------|----------------|----|
|       | <i>Ministry of Health considered changing their policy in regards to age of vaccination, weight at time of vaccination, and number of vaccinations given at once?</i>  | publicly available on the Medsafe website at the following address:<br><a href="https://medsafe.govt.nz/profs/PUArticles/December%202016/SuddenUnexpectedDeathInInfants.htm">https://medsafe.govt.nz/profs/PUArticles/December%202016/SuddenUnexpectedDeathInInfants.htm</a> .   |      |             |             |       |             |   |       |                 |   |       |                    |   |       |  |    |       |  |    |       |                |    |
| 3     | <i>has the C&amp;Y Epidemiology Services looked into these vaccine deaths and considered whether the other SIDS deaths may be attributed to vaccination as well?</i>   | This information is not held by the Ministry. You may wish to refer this part of your request to the New Zealand Child and Youth Epidemiology Service (NZCYES) ( <a href="mailto:nzcyes@otago.ac.nz">nzcyes@otago.ac.nz</a> ), otherwise, please refer to our response to Question 2.  |      |             |             |       |             |   |       |                 |   |       |                    |   |       |  |    |       |  |    |       |                |    |
| 4     | <i>Has the MOH told vaccine nurses and other vaccinators to warn parents that death may be a side effect of vaccination? And if not, why not?</i>  | No. Please refer to response to Question 2.  |      |             |             |       |             |   |       |                 |   |       |                    |   |       |  |    |       |  |    |       |                |    |
| 5     | <i>Have hospitals been warned to check for vaccination status of young children, in case of vaccine injury being misdiagnosed? If not, why not? If so, how many babies are presenting annually with vaccine injury to hospitals.</i> | <p>Please note that the Ministry is not responsible for assessing infants that are at risk. This is the responsibility of the medical professionals administering the vaccine.</p> <p>Summarised in the table below is the number of publicly funded hospital discharges of infants with an external cause code of <i>Bacterial vaccines, viral vaccines, rickettsial vaccines and protozoal vaccines causing adverse effects in therapeutic use</i>, where the external cause code has a condition onset code of 2, indicating that it happened before the patient was admitted. In 2018/19 there were 34 such events:</p> <p><b>Table 2. Publicly funded hospital discharges on infants in 2018/19</b></p> <table border="1"> <thead> <tr> <th>Code</th> <th>Description</th> <th>Total count</th> </tr> </thead> <tbody> <tr> <td>Y58.0</td> <td>BCG vaccine</td> <td>3</td> </tr> <tr> <td>Y58.4</td> <td>Tetanus vaccine</td> <td>2</td> </tr> <tr> <td>Y58.5</td> <td>Diphtheria vaccine</td> <td>4</td> </tr> <tr> <td>Y58.6</td> <td>Pertussis vaccine, including combinations with a pertussis component</td> <td>21</td> </tr> <tr> <td>Y58.9</td> <td>Other and unspecified bacterial vaccines</td> <td>11</td> </tr> <tr> <td>Y59.0</td> <td>Viral vaccines</td> <td>16</td> </tr> </tbody> </table> | Code | Description | Total count | Y58.0 | BCG vaccine | 3 | Y58.4 | Tetanus vaccine | 2 | Y58.5 | Diphtheria vaccine | 4 | Y58.6 | Pertussis vaccine, including combinations with a pertussis component | 21 | Y58.9 | Other and unspecified bacterial vaccines | 11 | Y59.0 | Viral vaccines | 16 |
| Code  | Description  | Total count  |      |             |             |       |             |   |       |                 |   |       |                    |   |       |  |    |       |  |    |       |                |    |
| Y58.0 | BCG vaccine  | 3  |      |             |             |       |             |   |       |                 |   |       |                    |   |       |  |    |       |  |    |       |                |    |
| Y58.4 | Tetanus vaccine  | 2  |      |             |             |       |             |   |       |                 |   |       |                    |   |       |  |    |       |  |    |       |                |    |
| Y58.5 | Diphtheria vaccine   | 4  |      |             |             |       |             |   |       |                 |   |       |                    |   |       |  |    |       |  |    |       |                |    |
| Y58.6 | Pertussis vaccine, including combinations with a pertussis component   | 21   |      |             |             |       |             |   |       |                 |   |       |                    |   |       |  |    |       |  |    |       |                |    |
| Y58.9 | Other and unspecified bacterial vaccines   | 11   |      |             |             |       |             |   |       |                 |   |       |                    |   |       |  |    |       |  |    |       |                |    |
| Y59.0 | Viral vaccines   | 16   |      |             |             |       |             |   |       |                 |   |       |                    |   |       |  |    |       |  |    |       |                |    |

| # | Requested information  | Response   |
|---|--|--|
|   |  | <div style="border: 1px solid black; width: fit-content; margin-bottom: 5px; padding: 2px;">57**</div> <p>**The total is greater than 34 because some people had multiple codes reported on the same record and are therefore counted in each category, but only once in the total.</p> <p>It is also important to note that an adverse event is not necessarily a vaccine injury. You may wish to refer this part of your request to the Accident Compensation Corporation (ACC) for further information, as ACC is responsible for 'treatment injury claims'. You can submit an online request to ACC at: <a href="https://acc.co.nz/contact/request-info/">https://acc.co.nz/contact/request-info/</a>.</p>   |
| 6 | <p><i>Please send me CARM data that shows ALL vaccine reactions that have been brought to CARM for the past five years.</i></p>  | <p>The Suspected Medicine Adverse Reaction Search (SMARS) is publicly available from the Medsafe website which will provide you information on suspected adverse reactions: <a href="https://www.medsafe.govt.nz/Projects/B1/ADRDisclaimer.asp">https://www.medsafe.govt.nz/Projects/B1/ADRDisclaimer.asp</a>.</p> <p>Please note that there are over 1,500 reports a year where a vaccine was suspected of causing a reaction, therefore, this part of your request will require refinement if you wish to request further information on vaccine-related adverse reactions.</p>  |
| 7 | <p><i>As there is some international research that casts doubt on the sterility of Infanrix-Hexa showing it to be highly contaminated with heavy metals, animal viruses and human DNA, what independent testing, if any, has the MOH carried out to ensure the safety and cleanliness of this vaccine?</i></p> | <p>The Ministry/Medsafe has not arranged for any independent testing of the Infanrix-hexa vaccine. As you may be aware, the Pharmaceutical Management Agency (PHARMAC) is responsible for the procurement of vaccines and holds contracts for the supply of funded vaccines. You may wish to contact PHARMAC for information pertaining to this part of your request: <a href="mailto:enquiry@pharmac.govt.nz">enquiry@pharmac.govt.nz</a></p> <p>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, effective, and of high quality. If Medsafe is concerned about the quality of a medicine, we can arrange for independent testing from the Therapeutic Goods Administration.</p> <p>Furthermore, 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:</p> |

| #  | Requested information  | Response  |
|----|--|---|
|    |  | <a href="https://medsafe.govt.nz/consumers/educational-material/Where%20Can%20I%20Find%20Info%20About%20Vaccines.asp">https://medsafe.govt.nz/consumers/educational-material/Where%20Can%20I%20Find%20Info%20About%20Vaccines.asp</a>   |
| 8  | <p><i>Bearing in mind that the Health Act 1956 states "the Ministry shall have the function of improving, promoting, and protecting public health." what is the MOH doing to protect infants from vaccine induced SIDS? Bearing in mind that two of the three vaccines contain aluminium, both as phosphate and hydroxide and that injected aluminium goes preferentially to the brain, what studies has the MOH done to ensure the injected aluminium is not causing brain stem injury and hence apnea?</i></p> | <p>The Ministry has not conducted any studies to 'ensure the injected aluminium is not causing brain stem injury and hence apnea'. Please refer to response to Question 2.</p>  |
| 9  | <p><i>What studies has the MOH done to compare the death rate from SIDS/SUDI in vaccinated and in non-vaccinated babies? Bearing in mind, two of the three vaccines contain aluminium, and both cause apnea, what studies does the MOH have to show the two vaccines in combination are safe?</i></p>  | <p>The Ministry does not conduct studies, there are published studies in the scientific literature referred to in the <i>Prescriber Update</i> article. Please refer to response to Question 2.</p>   |
| 10 | <p><i>What has MOH put in place to assess these infants at risk of apnea from vaccination?</i></p> <p><i>Please include correspondence and any relevant references in relation to SIDS and vaccination status that shows that Ministry of Health and the Child and Youth Epidemiology Service are aware that there may be</i></p>  | <p>This part of your request has been refused under section 18(e) of the Act, as the information requested does not exist. It is important to note that the Ministry is not responsible for assessing high-risk infants.</p> <p>Apnoea is frequently seen in preterm infants but can occur at any age. The association observed between immunisation of preterm infants and a transient increase or recurrence of apnoea after vaccination is known and described in the data sheets. Please note that a link has not been established between SIDS and immunisation. Deaths from SIDS are most common in the first few months of life, which is the same time when infants are receiving</p> |

| # | Requested information                                      | Response  |
|---|--|---|
|   | <p><i>causation between vaccination and SIDS/SUDI.</i></p> | <p>immunisations. This is why some have suggested that immunisation may be the cause of some SIDS deaths. There are 3 risk factors that increase a baby's risk of SUDI:</p> <ul style="list-style-type: none"> <li>• Infants sleeping on their side or front rather than on their back</li> <li>• Bed-sharing</li> <li>• The mother smoking in pregnancy</li> </ul> <p>Several studies have examined the relationship between SIDS and immunisation. Some early studies suggested a relationship existed, but more recent studies have shown that immunisation is associated with a lower risk of SIDS (<a href="https://hqsc.govt.nz/our-programmes/mrc/cymrc/information-for-parents-and-families/sudi-questions/">https://hqsc.govt.nz/our-programmes/mrc/cymrc/information-for-parents-and-families/sudi-questions/</a>).</p> |