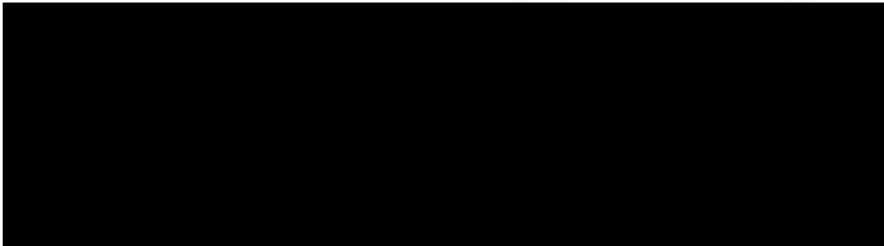


17 June 2019



Response to your request for official information

Thank you for your request of 18 May 2019 under the Official Information Act 1982 (the Act) for:

“Could you please supply copies of the reports for each clinical trial relied upon by Medsafe when approving for use by pregnant women any influenza vaccine currently approved by Medsafe.”

Clinical trials are used to investigate the efficacy and safety of medicines. There are other ways of studying medicines called observational studies in which the researcher does not control how human participants are assigned to different treatments. These studies can be used to investigate the effectiveness and safety of medicines.

There are very few medicines that are specifically indicated for use in pregnancy, an example would be folic acid. This is because most clinical trials are not performed on pregnant women. In fact, pregnant women are usually excluded from clinical trials.

Influenza vaccines are not specifically indicated in pregnancy, that is, the indications described in the data sheet (product information) do not specifically mention ‘use in pregnancy’. The indications say ‘use in adults and/or children’ from a particular age. To see whether a medicine might be safe to use in pregnancy, you need to check if it is contraindicated and the section on use in pregnancy in the data sheet. If a medicine is contraindicated in pregnancy, it means there is good evidence that it can cause harm, but even so, this evidence is usually from observational studies not clinical trials. The pregnancy section gives an overview of the current knowledge about use in pregnancy so that the woman can make a choice about using the medicine in pregnancy in conjunction with her healthcare professionals.

The currently approved influenza vaccines in New Zealand are:

- Influvac Tetra (funded for eligible adults and children aged 3 years or older)
- Fluarix Tetra (funded for eligible children aged 6–35 months of age)
- Afluria Quad
- FluQuadri

These do not have specific indications for pregnant women – they are indicated for use in adults and children. The vaccines are also not specifically contraindicated during pregnancy. Therefore, when approving the vaccines for use in New Zealand, Medsafe did not rely on data from clinical trials conducted during pregnancy. You can find further information on these vaccines on the Medsafe website (www.medsafe.govt.nz).

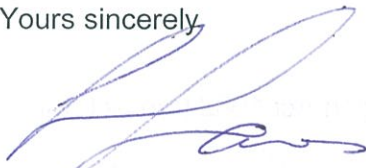
For your reference, I have also included links to the data sheets for these vaccines:

- <https://www.medsafe.govt.nz/profs/datasheet/i/InfluvacTetrainj2019.pdf> (Influvac Tetra)
- <https://www.medsafe.govt.nz/profs/datasheet/f/fluarixtetrainj.pdf> (Fluarix Tetra)
- <https://www.medsafe.govt.nz/profs/datasheet/a/Afluriainj.pdf> (Afluria Quad)
- <https://www.medsafe.govt.nz/profs/datasheet/f/fluquadriinj.pdf> (FluQuadri)

You can find more information on flu vaccination in pregnancy in the immunisation handbook (<https://www.health.govt.nz/publication/immunisation-handbook-2017>). You can find the published observation studies on flu vaccine in pregnancy by searching in PubMed (<https://www.ncbi.nlm.nih.gov/pubmed/>).

I trust this information fulfils your request. Please note this response (with your personal details removed) may be published on the Medsafe website.

Yours sincerely,



Chris James
Group Manager
Medsafe