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25 August 2021

Paul Jones

By email: fyi-request-16233-4ab7df68@requests.fyi.org.nz Ref: H202109584

Tēnā koe Paul,

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 29 July 2021 for the documentation and evidence supporting the official statements regarding the Pfizer vaccine (Comirnaty). I will respond to each part of your request in turn:

"With reference to the following link;

https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novelcoronavirus/covid-19-vaccines/covid-19-getting-vaccine/covid-19-pregnancy-andbreastfeeding-vaccine-advice

Under section Breastfeeding it states; "If you're breastfeeding (as with all vaccines on the New Zealand Immunisation Schedule), there are no safety concerns about getting the Pfizer vaccine (Comirnaty)."

The statement above is a summary of the advice from numerous professional organisations including: The Royal Australian & New Zealand College of Obstetricians & Gynaecologists; Public Health England; American College of Obstetricians and Gynaecologists, and the Society of Obstetricians and Gynaecologists Canada. The advice was published by the Immunisation Advisory Centre in consultation with the Ministry of Health.

Breastfeeding is not a contraindication to vaccination to any vaccines on the New Zealand Immunisation Schedule which can be viewed at the following link: <u>www.immune.org.nz/sites/default/files/resources/Written%20Resources/AdministrationBreas</u> <u>tfeedingImac20210813V01Final.pdf</u>

The relevant statement is provided below:

"A woman who is breastfeeding can be immunised safely with both inactive vaccines such as tetanus, hepatitis B, and human papillomavirus vaccines, and live vaccines such as measles/mumps/rubella (MMR) and varicella (chickenpox) vaccines." The Pfizer vaccine is not excreted in the breast milk: www.jamanetwork.com/journals/jamapediatrics/fullarticle/2781679

Therefore, there is no evidence that the baby will receive any vaccine by being breastfed.

Further information regarding breastfeeding after vaccination against COVID-19 can be found in a recent Nature article here: <u>www.nature.com/articles/d41586-021-01680-x</u>

"Pfizers document released in the following link;

http://scanmail.trustwave.com/?c=15517&d=-PaA4eSyfI0vyJ5wkTCW5E4rxn_A5fDgSXRMOtBSkQ&u=http%3a%2f%2flabeling%2e pfizer%2ecom%2fShowLabeling%2easpx%3fid%3d14471%26format%3dpdf

On page 32, section "11.2 Lactation" states; "Risk Summary" "Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion."

This means Pfizer own documentation is contrary to the Ministry of Health's statements and understanding of the above as if no data is available then you can't make any claims.""

The reason why the statement from the manufacture says that data is available to assess the effects of the Pfizer vaccine on the breastfed infant or milk production is because they are referring to the lack of randomised trials comparing breastfeeding women who received the vaccine to breastfeeding women who did not receive the vaccine. This is because pregnant and breastfeeding women were excluded from the initial randomised controlled trials. However, this does not mean that there is no evidence supporting the use of vaccination in breastfeeding women. The recommendation to use Pfizer in breastfeeding women in New Zealand is based on a wide range of sources including the following: recommendations from professional bodies as above, the known pharmacology of the type of vaccine, in particular the fact that the vaccine is not a live virus, rather is a segment of modified RNA, the safety of other similar vaccines administered to pregnant women and monitoring of the large number of women who have received vaccines while breastfeeding.

For your reference, the Ministry's COVID-19 vaccine advice for women who are pregnant, breastfeeding and trying for a baby as at 16 June 2021, is publicly available at: <a href="http://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/

Under section 28(3) of the Act you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Nākū noa, nā

Gul Hall

Gill Hall Group Manager COVID-19 Science and Insights