MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T +64 4 496 2000
W www.medsafe.govt.nz

7 April 2021

[redacted]

By email: [redacted]
Ref: H202102876

Dear [redacted]

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 14 March 2021 for information about the Comirnaty vaccine.

Responses to your questions are set out below.

> *"OIA: Comirnaty is a mRNA-based (messenger ribonucleic acid) vaccine that, when administered, induces cells to create an extra protein. INFORMATION REQUESTED:*
> *1. How long does that created extra protein last in the body after the mRNA-based vaccine injection? Is the extra protein permanently there?"*

The SARS-CoV-2 S protein, which is created following injection of the mRNA-based vaccine, is in this context referred to as 'antigen'. In human studies, the focus is the duration of the immune response to the antigen. The antigen is not expected to last longer than two weeks, based on animal experiments.

> *2. What are the effects of that extra protein on the body, apart from immunity?*

The sole function of the SARS-CoV-2 S protein, associated with the mRNA vaccine, is to elicit an immune response in the body.

> *3. What functions does that extra protein in the body perform other than immunity?*

As part of the corona virus, the S protein is thought to be important in allowing the virus to enter cells and then replicate.

> *4. How (if anything) does that extra protein add to or change the DNA of the human receiving the vaccine?*

The mRNA does not enter the cell nucleus and does not add to or change the DNA (www.medsafe.govt.nz/COVID-19/mRNA-vaccines.asp).

> *5. Do traditional vaccines (containing a weak or dead virus) induce cells of the person receiving the vaccine to create an extra protein in a similar way to mRNA-based vaccines?*

In vaccines containing parts of a virus or bacterium, those parts are the antigen that leads to the body producing an immune response. There is no replication of the virus or bacterium.

In vaccines containing a weak virus (so-called live attenuated vaccines), the recipient becomes infected (the virus replicates) and their body produces antigens (new proteins) resulting in an immune response.

Non-replicating mRNA vaccines (such as the Comirnaty mRNA vaccine) do not include the code allowing viral replication. The cells of the person receiving the mRNA vaccine produce the antigen in response to the injected mRNA.

6. What are the differences in how and for how long an extra protein is created in mRNA-based vaccines compared to traditional vaccines (containing a weak or dead virus)?

As noted in the response to question 5 above, when administered a dead (inactivated) virus, the vaccine recipient does not generate the antigen. Rather, the dead virus is the antigen.

Recipients of live-attenuated viral vaccines would be expected to generate antigen for longer than recipients of non-replicating mRNA vaccines. However, individual responses to different vaccines can vary.

7. What are the risks of having this extra protein in the body?

The study programme (including animal and human studies) supporting the Comirnaty mRNA vaccine shows the vaccine to be acceptably safe and effective. Identified risks are contained in the vaccine's Risk Management Plan at: www.medsafe.govt.nz/COVID-19/Comirnaty-RMP.pdf

I trust this information fulfils your request. 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.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

Chris James
Group Manager
Medsafe