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

6 April 2022

Chuck Schooner

By email: fyi-request-18233-b01c097b@requests.fyi.org.nz
Ref: H202201546

Tēnā koe Chuck

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 10 and 16 February 2022. On 10 March 2022, the first part of your request was responded to.
You requested:

> *"So just a follow up on this there was one confirmed report of poisoning and one other Medsafe are aware of so "Two" in total.*
> *So what is the criteria for a product to be removed?*
> *Please provide all the reporting/documents that linked this product to being removed and the associated recommendation by Medsafe.*
> *I want to see the process that Medsafe went through and the evidence used to justify stopping this product being used.*
> *Did the person die?*
> *If not there was one person in total that had a reaction?*
> *What is the criteria for a medicine to stop being prescribed?*
> *- one death?*
> *- heart conditions?*
> *- two deaths?*
> *- one reaction as per Goree product being removed*
> *- Bells Palsy?*
> *- 13 year olds death being investigated? Would that warrant a roll out being stopped?*
> *- miscarriages?*
> *- auto immune disorders?*
> *What criteria needs to be met for a product to be removed? Please provide the Goree reporting so I can understand the criteria.*

Medsafe is the New Zealand Medicines and Medical Devices Safety Authority and administers the requirements of the Medicines Act 1981. This law requires that products intended for a therapeutic purpose are assessed and approved by Medsafe (under delegation from the Minister of Health) unless there is a legislative exemption. The Medicines Act can be viewed at: www.legislation.govt.nz/act/public/1981/0118/latest/DLM53790.html. The Medicines Act permits the classification of medicines as: 'prescription', 'restricted' (pharmacist-only) and 'pharmacy-only'. The Medicines Act also enables the removal of products from the market should they pose a safety issue. Medsafe received a report about harm arising from the use of the Goree product and found it contained both lead and mercury at above prescription medicine levels.

In this instance, the primary reason for the product being removed was patient safety. This product was being marketed as a cosmetic, it contained high levels of mercury and lead, and a

person using the product was reported as being managed by their GP for suspected mercury poisoning. Although marketed as a cosmetic, the mercury and lead present were at levels that would make the product a prescription medicine. The product did not have consent for sale, advertising or distribution as a medicine, so sale of the product was also a breach of section 20 of the Medicines Act. The presence of lead and mercury in the product was not identified on the product labels. The dangers associated with use of the product were specified in the Alert Communication published at: www.medsafe.govt.nz/safety/Alerts/skin-whitening-cream.asp.

In this instance the process followed was:

- A GP reported a case of suspected mercury poisoning to the local district health board public health unit (DHB PHU).
- The DHB PHU obtained some of the product that was suspected to have caused the poisoning.
- The DHB PHU found an overseas alert online about the product and alerted Product Safety at Medsafe.
- Medsafe assisted the DHB to send a sample of the product to ESR for testing.
- The patient identified the business that supplied the product.
- Medsafe staff visited the business and located this product and some other similar products of concern.
- These products were detained, and samples of product from this location were also sent to ESR for testing.
- The testing results identified that the products contained high levels of mercury and lead.
- Medsafe contacted the Ministry for the Environment about the mercury content in the products as it was working to ratify the Minamata Convention, an international treaty designed to protect human health and the environment, including reducing the release of mercury and mercury compounds.
- Medsafe contacted the Environmental Protection Agency (EPA) as the product was marketed as a cosmetic and the Cosmetic Product Group Standard sits with EPA.
- As it was not possible to identify who had imported and/or was selling such skin whitening products, a Director-General's Privileged Statement under section 98 of the Medicines Act was published as an alert communication on the Medsafe website to warn users of the potential dangers associated with use of the product.

Medsafe is aware of two reports of harm following use of this product.

This product was not sold as a medicine, nor was it prescribed. It was sold as a cosmetic and self-selected by customers. Both the purpose for the product, skin whitening, and the content, meant the product was a medicine and not a cosmetic.

The process for removal of an approved medicine from the market is different. It involves a review of the risk-benefit of the product following reported adverse events where a signal is identified that the product has potential for harm. A description of the process followed when Reductil, a prescription medicine for weight loss was withdrawn from the New Zealand market in 2010, is published at: www.medsafe.govt.nz/hot/media/2010/SibutramineOct2010.asp.

Please find attached to this letter copies of the key documents that informed the regulatory action taken. The documents are outlined in Appendix 1 and copies are enclosed. The table in Appendix 1 outlines my decisions on the release of each document. I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

- Please provide any and all information that contradicts Medsafes own data that vaccination is safe for pregnant woman because clearly there is a risk due to real world data
Are pregnant woman being warned that they may lose there baby due to the vaccine? If not - why not?
How many more premature deaths are required before Medsafe decide that this isn't safe for the pregnant woman and their unborn child."

The Ministry does not hold any information that 'contradicts' its own data. As you have been advised, the Act does not support requests where an opinion, comment, argument, or hypothetical statement is put to the Ministry for response, couched as a request for information. These questions are therefore refused under section 18(g) of the Act on the grounds that the information sought is not held by the Ministry.

However, the Ministry has published a range of information about pregnancy and COVID-19 vaccination. Section 5.5.4 of the *Immunisation Handbook* addresses pregnancy and vaccination with the Pfizer Comirnaty vaccine. The Handbook, which provides references to a range of reputable peer-reviewed scientific literature, found no safety concerns for pregnant women with the Comirnaty vaccine and recommended they be routinely vaccinated. It noted that: "The risk of an adverse outcomes from COVID-19 infection during pregnancy is significantly higher compared to non-pregnant adults." It is available at: www.health.govt.nz/our-work/immunisation-handbook-2020/5-coronavirus-disease-covid-19#23-5.

The Ministry has also published a review of scientific literature that found no link between COVID-19 vaccination and an increased risk of miscarriage. It is available at: www.health.govt.nz/system/files/documents/pages/csu-13-sept-2021-vaccination-in-pregnancy-is-not-associated-with-miscarriage.pdf. Additionally, the Immunisation Advisory Centre at the University of Auckland has published advice for health professionals that recommends COVID-19 vaccination for pregnant women. It is available at: https://covid.immune.org.nz/sites/default/files/2022-02/Pregnancy_COVID19%20and%20COVID19%20vaccination_HP_2022Feb15.pdf.

Comirnaty vaccine like all medicines can cause side effects in some people. It is approved because the expected benefits outweigh the risk of side effects for the population as a whole. Nevertheless there are some people for whom the vaccine is contraindicated (should not be used), these are people who have a severe allergic reaction to the vaccine. The product Goree which is referred to above has not demonstrated any benefit, therefore the balance of benefits and risks is unfavourable, and this is the reason for the difference in regulatory actions.

I trust this 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 of Health website at: www.health.govt.nz/about-ministry/information-releases.

Nāku noa, nā

Chris James
Group Manager
Medsafe

Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	N/A	Overseas regulator alert	Released in full.
2	2 December 2021	Letter to store owner linked to the initial complaint details	Some information withheld under the following under section 9(2)(a) of the Act, to protect the privacy of natural persons, and section 9(2)(b)(ii) as its release would likely unreasonably prejudice the commercial position of the person who supplied the information.
3	20 December 2021	Memo	Information deemed out of scope has been excluded
4	22 December 2021	Memo to Director-General of Health requesting approval to publish Privileged Statement under s98 of the Medicines Act 1981	Some information withheld under section 9(2)(a).