Close

Two Types of Cosmetic Products Found Adulterated

HEALTH PRODUCTS FOUND ADULTERATED

The Ministry of Health would like to alert members of the public to **2** types of cosmetic product which have been tested by the Laboratory of **Pharmacy Section, Scientific Laboratory Services, Ministry of Health** and found to be adulterated with undeclared, potent western medicine.

The affected health products are listed as below:

No.	Name of product	Manufacturer	Adulterated with
1.	Goree Beauty Cream with Lycopene	H Pharmacy Pakistan	**Mercury**
2.	Goree Day & Night Whitening Cream Oil Free	H Pharmacy Pakistan	**Mercury**

Goree Beauty Cream with Lycopene

Goree Day & Night Whitening Cream Oil Free

The adulterant found in these products can cause adverse effects that are potentially hazardous to the people using them.

Mercury is a potent ingredient that is prohibited in cosmetic products as stipulated in the *Medicines (Cosmetic Products) Regulations 2007.*

Mercury is prohibited in cosmetic products due to its hazardous effects on human health. It is readily absorbed through the skin on topical application and tends to accumulate in the body. Exposure to mercury can cause skin rashes, memory loss and muscle weakness while high exposures may result in damage to the brain and kidneys. It is also extremely toxic to unborn children.

The Ministry of Health has not issued any approval for the importation for the sale of these products and/or Cosmetic Notification Acknowledgement Letter for the sale of the rest of affected products. Following these findings, the products are not allowed to be imported and sold in Brunei Darussalam.

Members of the public who have purchased or used these products are advised to stop using them immediately. They should also consult a medical practitioner if they feel unwell or experience any undesirable reactions as a result of using them.

Members of the public involved in the retail of these products (including online retail such as through Facebook, etc.) are hereby reminded that it is an offence under the Medicines (Cosmetic Products) Regulations, 2007 to import and market cosmetic products in the local market without a Cosmetic Product Notification Acknowledgement Letter issued by the Authority, where the penalty for contravening these regulations upon conviction, is a fine not exceeding $5,000, imprisonment for a term not exceeding two years or both.

The Ministry of Health would also like to call upon the public for their cooperation to report to the Pharmacy Enforcement Section if any of these products are still found on the market in this country.

For further information and communication, the public may contact the Pharmacy Enforcement Section at 2393298 extension 208; send an e-mail to pharmacy.enforcement@moh.gov.bn (mailto:pharmacy.enforcement@moh.gov.bn); go directly to 1st Floor, Department of Pharmaceutical Services' Building, Kg. Madaras, Mukim Gadong A; or call the Talian Darussalam 123.

- E N D -

Reference : KK/PR/3

Date : 26 March 2018 / 8 Rejab 1439H

Close

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W www.medsafe.govt.nz

2 December 2021

s 9(2)(a)

AUCKLAND
By email: s 9(2)(a)

Dear s 9(2)(a)

Re: Sale of prescription medicine
Our ref: s 9(2)(b)(ii)

I write further to my visit to your s 9(2)(a), s 9(2)(b)(ii) store yesterday, at 10.30am, alongside my colleague Team Leader Simon Williamson,

Medsafe is a business unit of the Ministry of Health and is the regulatory authority responsible for administering the medicine legislation in New Zealand. This includes the Medicines Act 1981 ("The Act").

On 16 April 2018 I, Scott Read of Medsafe, Ministry of Health, was appointed to be an officer for the purposes of the Act pursuant to section 15(1) of the Act, and the State Sector Act 1988. My duty as an officer is to exercise the powers and functions conferred on me by the Act.

Store visit

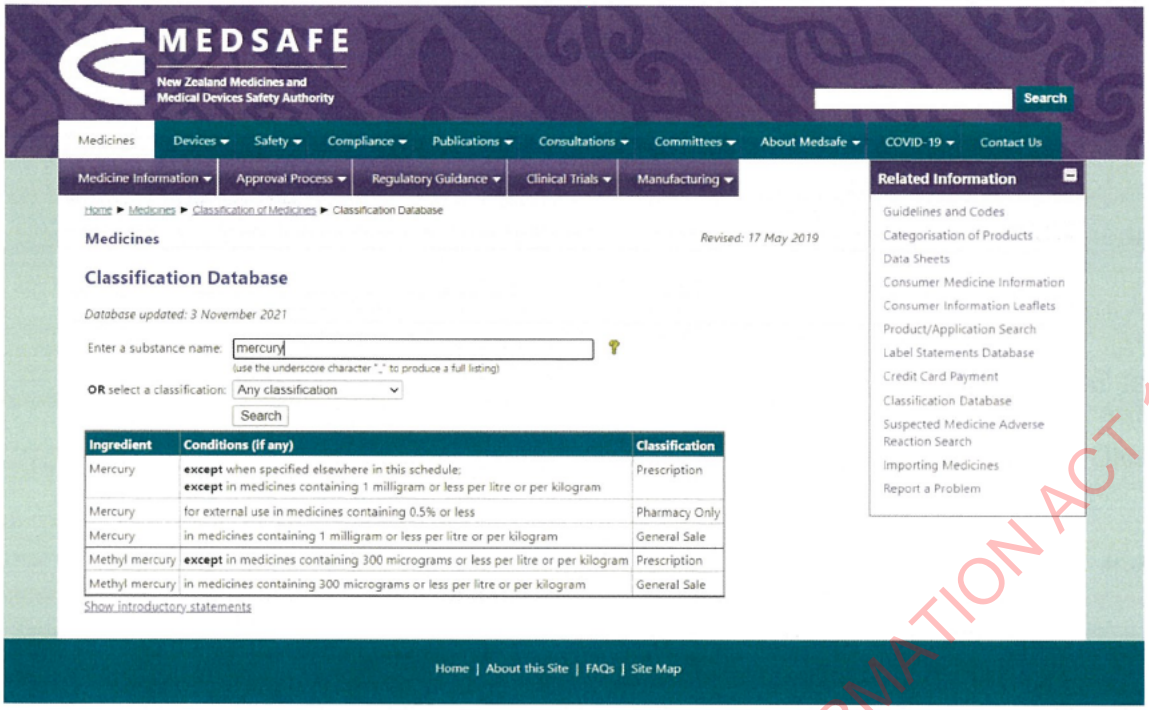
My colleague Mr Williamson and I visited your s 9(2)(a), s 9(2)(b)(ii) store at around 10.30am yesterday. Thank you to your staff who were cooperative and helpful. You were not present, but I was able to speak to you briefly by phone during our visit.

We explained the purpose of our visit. It recently came to Medsafe's attention that a customer of yours had recently purchased from your store the product *Goree Beauty Cream with lycopene* – a whitening cream product.

s 9(2)(a) later became unwell and saw s 9(2)(a) doctor who suspected s 9(2)(a) may have mercury poisoning. The GP raised the issue with his local Public Health Unit who in turn contacted Medsafe.

We arranged for the product s 9(2)(a) used to be laboratory tested by the ESR. The result confirmed the product was found to contain mercury at a high level (24900ppm).

At a level in excess of 1ppm, mercury is scheduled as a prescription medicine in New Zealand.



We therefore had reasonable grounds to exercise our statutory powers at your store.

We located in the store:

- **12 boxes of Goree Beauty Cream with lycopene**

As we have reasonable grounds to suspect that other whitening creams for sale may contain heavy metals as well, we advised you that we would detain them and send samples away for to ESR for laboratory testing to clarify this.

Therefore, we **detained** the following similar products for testing:

Out of scope

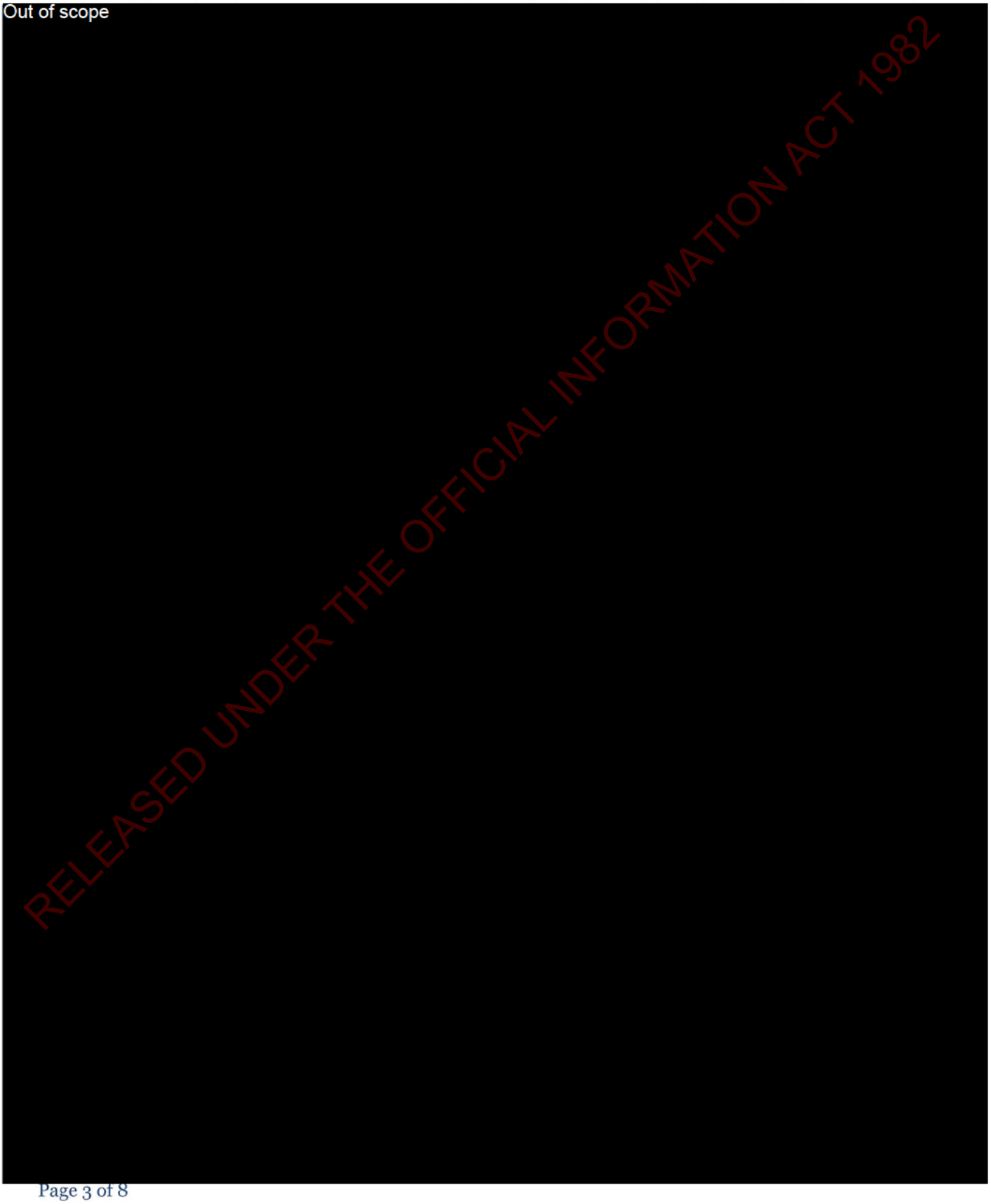
- **Goree Day and Night Beauty Cream Oil free x 6 boxes**
- **Golden Pearl Beauty Cream x 9 boxes**

Out of scope

During the visit, we provided you we issued you with the two letters by hand explaining our statutory authority to search the premises, examine products, take photographs, and detain product for assessment, and that outlined the number of products we had detained from the store.

You advised that you sourced some of the products from overseas through the mail, but some was sourced from local markets.

Out of scope



Out of scope

Consideration

Medicines and related products (a related product is a product that is primarily a food, dentifrice or cosmetic, but has a secondary therapeutic use) need consent by means of gazettal before they can be distributed/sold/advertised, and that consent is specific to the NZ 'sponsor' and the product that has consent. The sponsor is the person or company legally responsible having the medicine consented for sale, distribution and advertising in New Zealand, and placing the product on the market in New Zealand.

Your store is not licensed as a pharmacy. Unless permitted by regulations made under the Act, it is unlawful to sell by retail, or supply in circumstances corresponding to retail sale, or distribute by way of gift or loan or sample or in any other way, prescription medicines, restricted (pharmacist only), or pharmacy only medicines (section 18 of the Act). The penalty involved for doing so is, on conviction, a fine not exceeding $40,000 or a term of imprisonment not exceeding six months.

Medicines that do not have the consent of the Minister of Health for sale, distribution, or advertising in New Zealand and are considered to be "*new medicines*". It is illegal to sell, distribute by way of gift or loan or sample or in any other way, or advertise the availability of a *new medicine* (unapproved medicine) and to do so breaches section 20 of the Act. The penalty on successful conviction for this offence is a fine not exceeding $100,000 for a body corporate, and in the case of an individual, imprisonment for a term not exceeding 6 months or a fine not exceeding $20,000.

Under section 43 of the Medicines Act, no person shall import, procure, receive, store, use or otherwise have in their possession any prescription medicine without reasonable excuse

– such as a being a licensed pharmacy, or a person who is authorised to supply and administer any specified class or description of prescription medicine. The penalty for doing so is, on conviction, a fine not exceeding $500 or a term of imprisonment not exceeding three months.

General sale medicines
You may sell *general sale* medicines that have approval and are consented for distribution in New Zealand as a medicine. You must purchase any such general sale medicines through the legitimate New Zealand supply chain, i.e., from a person or company that is licensed to sell them in New Zealand.

If you were to parallel import general sale medicines and sell or distribute them, the products would not have gone through the legitimate New Zealand supply chain and their sale or distribution would be unlawful and in contravention of section 20 of the Act.

Seizure

This letter is to formally notify you that we have seized the **Goree Beauty Cream with lycopene product, the** Out of scope **listed above**, pursuant to section 63(2)(I) of the Act, as we have reasonable grounds to believe that offences against the Act have occurred. Relevant sections of the Act are attached at Appendix 1.

I advise that section 65(1) of The Act provides that any person who has an interest in the items seized May, within seven days of notification of seizure, make application to the District Court to apply for an order –

> *(a) That the seizure be disallowed and that the article be returned or otherwise be made available to him.*
> *(b) That the Crown shall pay to him such sum by way of value of the substance or article resulting from its seizure, detention, or removal as the Crown thinks fit.*

I further advise that if no application for disallowance is received within seven days then the articles become property of the Crown.

Seller's responsibility

If you continue to purchase and distribute similar products it is your responsibility to ensure that the product, sale, labelling and advertising, including websites, complies with New Zealand legislation.

We have not reviewed all of the health products that you have in stock. Just because we have not reviewed them or have not seized them does not mean that they comply with the relevant legislation. I recommend that you review all your products to ensure that you advertise and sell them in accordance with the law.

I encourage you to review your processes to ensure that any medicinal products that you purchase, import, advertise, sell or distribute comply with the Medicines Act 1981 and its regulations.

A number of regulatory consultants provide independent regulatory advice, clinical and other consultancy services to the therapeutic sector in New Zealand. A link to such consultants can be found on the Medsafe website: http://www.medsafe.govt.nz/regulatory/consultants.

I also attach for you the website link for the Medsafe classifications database: http://www.medsafe.govt.nz/profs/class/classintro.asp.

Testing
Once the detained whitening products have been tested by ESR and the results reported to Medsafe, we will be in contact again.

Immediate action required of you
Please review the above information and take the following **immediate** action in order to avoid any continuing offences:

- Review your businesses stock in light of the above information
- Please confirm to Medsafe the addresses of all stores your business operates as well as the warehouse location.
- Immediately cease importing, advertising, and selling Goree Beauty Cream with lycopene, and all other medicines identified.
- Put aside any existing stock you may still hold of Goree Beauty Cream and any of the other products listed above, until ESR testing is complete, and advise Medsafe of the numbers of products put aside. These products must not be sold. We can arrange to further liaise with you in relation to such items.
- Please provide Medsafe with sales figures for all Goree Beauty Cream items you have sold in the past 12 months **as soon as possible**
- Remove from your website and any online platforms or social media pages you operate, and any advertising in relation to Goree Beauty Cream and all other medicines identified
- Respond to this letter, by email, no later than **7 December 2021**, to advise us of the review/action you are taking to ensure compliance with New Zealand law.

Please acknowledge receipt of this letter by return email.

Thank you for your assistance.

Yours sincerely

Scott Read
Senior Investigator
Medsafe, Ministry of Health
Investigation and Enforcement
Ph: s 9(2)(a) [redacted]
Email: scott.read@health.govt.nz

Appendix 1

43 Restrictions on possession of prescription medicines

(1)
No person shall, without reasonable excuse, import, procure, receive, store, use, or otherwise have in his possession, any prescription medicine.
(2)
Without limiting the meaning of the expression reasonable excuse in subsection (1), a person has a reasonable excuse for the purpose of that subsection if—
(a)
the possession or act that might otherwise be a contravention of that subsection—
(i)
is that of a person, licensed or otherwise authorised under this Act or any regulations made under this Act, to manufacture, sell, supply, pack, or administer the medicine or to be in possession of it; and
(ii)
is necessary as incidental to the business, calling, or purpose for which the person is so licensed or otherwise authorised; or
(b)
the possession or act that might otherwise be a contravention of that subsection—
(i)
is that of a carrier, or an employee of a carrier; and
(ii)
is necessary or incidental to the business of that carrier; or
(c)
the possession or act that might otherwise be a contravention of that subsection—
(i)
is that of a person to whom the medicine has been lawfully supplied for his or her use, or for use by any other person, as a patient under the care of an authorised prescriber or a delegated prescriber or in accordance with a standing order, and who does not have in his or her possession any other supplies of a prescription medicine prescribed or supplied for the same purpose by another authorised prescriber or delegated prescriber or in accordance with a standing order; and
(ii)
is necessary or incidental to such use; or
(d)
the possession or act that might otherwise be a contravention of that subsection—
(i)
is that of a person who has possession of the medicine only for the purpose of administering it to the person for whom it has been prescribed; and
(ii)
is necessary or incidental to that purpose; or
(e)
the possession or act that might otherwise be a contravention of that subsection—
(i)
is that of a person in the service of the Crown; and
(ii)
is necessary or incidental to the performance of that person's duties.
(3)
In any proceedings under this section against any person in which it is proved that that person procured, received, stored, used, or otherwise had in his possession any prescription medicine, the onus of proving that he had a reasonable excuse (whether by reason of the fact that 1 or more of the provisions of paragraphs (a) to (e) of subsection (2) apply to his case or otherwise) shall lie on the defendant.
(4)
In any proceedings under this section, the fact that the defendant did not know that the medicine that is the subject of the prosecution was a prescription medicine is not by itself a reasonable excuse.
(5)
Every person commits an offence against this Act who contravenes subsection (1).

20 Restrictions on sale or supply of new medicines

(1) Except as provided in sections 25, 26(4), 28, 30, 31, and 32, this section applies to new medicines.
(2) No person shall—
(a) sell; or
(b) distribute by way of gift or loan or sample or in any other way; or
(c) advertise the availability of—
any medicine to which this section applies before the consent or provisional consent of the Minister to the distribution of the medicine has been notified in the Gazette, or otherwise than in accordance with such conditions as may be imposed by the Minister on giving his consent or provisional consent and notified in the Gazette.
(3) No consent given under this section shall be deemed to warrant the safety or efficacy of the medicine to which the consent relates.
(4) A person who contravenes subsection (2) commits an offence, and is liable on conviction—
(a) in the case of an individual, to imprisonment for a term not exceeding 6 months or a fine not exceeding $20,000:
(b) in the case of a body corporate, to a fine not exceeding $100,000.
(5) In any proceedings for an offence against subsection (4) in which it is alleged that this section applies to a medicine by reason of subsection (1), it shall be presumed that the medicine is a medicine to which this section applies until the contrary is proved.

18 Sale of medicines by retail

(1)

Except as provided in sections 25, 27, and 30 to 33, or as may be permitted by regulations made under this Act, no person shall, in the course of any business carried on by that person, sell by retail, or supply in circumstances corresponding to retail sale, or distribute by way of gift or loan or sample or in any other way,—

(a)

any prescription medicine unless—

(i)

the medicine is sold, supplied, or distributed by a pharmacist in a pharmacy or hospital; or

(ii)

the medicine is supplied in accordance with a standing order by a person who is authorised to supply and administer any specified class or description of prescription medicine under that standing order; or

(aa)

[Repealed]

(b)

any restricted medicine unless the medicine is sold, supplied, or distributed by a pharmacist in a pharmacy or hospital; or

(c)

any pharmacy-only medicine unless the medicine is sold, supplied, or distributed by—

(i)

a person under the supervision of a pharmacist in a pharmacy or a hospital; or

(ii)

a person who sells, supplies, or distributes the medicine in any shop described in section 51(2) and in accordance with a licence issued under Part 3.

(2)

No person may sell by retail any prescription medicine otherwise than under a prescription given by an authorised prescriber, a veterinarian, or a delegated prescriber.

(2A)

No person may supply, in circumstances corresponding to retail sale, any prescription medicine otherwise than—

(a)

under a prescription given by an authorised prescriber, a veterinarian, or a delegated prescriber; or

(b)

in accordance with a standing order.

(2B)

Despite subsections (2) and (2A), a person may sell by retail, or supply, in circumstances corresponding to retail sale, any prescription medicine, where permitted by section 25 or section 30 or section 31 or section 69 or by regulations made under this Act.

(3)

Except as may be permitted by regulations made under this Act, no person shall hawk any prescription medicine or restricted medicine or pharmacy-only medicine—

(a)

from house to house; or

(b)

in any public place within the meaning of section 2 of the Summary Offences Act 1981,—

otherwise than pursuant to any authority to do so expressly conferred by a licence held by him under Part 3, and in accordance with any conditions or restrictions specified in the licence.

(4)

Except as may be permitted by regulations made under this Act, no person shall sell any medicine by means of an automatic vending machine or by auctioning the medicine.

(5)

Every person who sells or supplies or distributes a prescription medicine in contravention of subsection (1) commits an offence and is liable to imprisonment for a term not exceeding 6 months or a fine not exceeding $40,000.

(6)

Every person commits an offence against this Act who contravenes any of the provisions of this section (otherwise than in circumstances that constitute an offence against subsection (5)).

DRAFT Memo

Date:	20 December 2021
To:	Derek Fitzgerald, Compliance Branch Manager Kathy Daly, Principal Technical Specialist
Copy to:	Simon Williamson, Team Leader, Investigation and Enforcement Team (IET), Auckland
From:	Scott Read, Senior Investigator, IET Auckland
Subject:	Issue of a s98 safety communication warning the public about the presentation of skin whitening cream products containing undeclared mercury
For your:	Review/Decision

Summary

The purpose of this memo is to:

- Further brief you about the ongoing enforcement investigation into the supply of a presentation of skin whitening products found to contain mercury
- Ask you to review a draft s98 safety communication in order to warn the public about the risk to health posed by such products.

Background

As discussed, Medsafe was alerted to this issue by the Bay of Plenty DHB Public Health Unit, after a local GP had reported a case of potential mercury poisoning in a patient. Information gathered by the DHB PHU found that the patient had used the product ***Goree Beauty Cream with Lycopene***.

Some overseas regulators have previously produced an alert that *Goree Beauty Cream with Lycopene,* as well as *Goree Day and Night Beauty Cream Oil Free,* are adulterated with (undeclared) mercury.

Product Safety arranged for the remainder of the *Goree Beauty Cream with Lycopene* product used by the patient in this case to be sent by the DHB PHU directly to the Institute of Environmental Science and Research (ESR) to expedite testing. The product was found to contain mercury at a level of 24900ppm (2.49%).

MEA2101

Parameter tested	Results
Aluminium - Total*	144 ppm
Arsenic - Total*	0.09 ppm
Copper - Total*	0.7 ppm
Iron - Total*	< 3 ppm
Lead - Total*	< 0.1 ppm
Manganese - Total*	< 0.1 ppm
Mercury - Total*	24900 ppm
Zinc - Total*	< 1 ppm

Medsafe IET staff seized *Goree Beauty Cream with Lycopene* product from a business location identified by the patient. The business was highly cooperative. The proprietor is of the view that these products are widely available on the internet, and she sourced them from a local South Auckland flea market (which is currently closed at the red CP Framework level).

In addition, the IET located 6 other similar products of interest and detained them in order to have them laboratory tested for the presence of heavy metals by the ESR. These were:

- **Goree Day and Night Beauty Cream Oil Free**

Out of scope

- **Golden Pearl Beauty Cream**

Out of scope

Accompanying promotional material in product packaging

Goree Beauty Cream with Lycopene material states:

> *…absorbs in the skin and treat[s] damage[d] cells. It contains vitamin B3 that makes skin beautiful and shiny. Due to the presence of lycopene it is non-poisonous, non-irritative with the best anti-oxidant properties so it keeps the skin moisture, recover all skin damages, eliminates bacteria and refreshes the skin tone. It can be used on normal, sensitive and pigmented skin. High-quality skin enhancing herbs helps to remove dark circles and freckles and brings back the natural glow of the skin. The composition of Goree beauty cream has been developed under the expert's supervision on the latest plant to ensure the quality standards of product.*

Goree Day and Night Beauty Cream Oil Free states:

> *…whitening cream is specially formulated from a mixture of different herbs for oily skin. Its control of the skin in 5 days n whitens it. It also repairs skin damages, low shiny skin n makes it soft and glowing. Natural ingredients included in the … cream absorb in skin and stimulate cells by eliminating excess amount of sweat. With its regular use; scars of burning, wounds and the nail acne completely disappears.*

Out of scope

Golden Pearl Beauty Cream states:

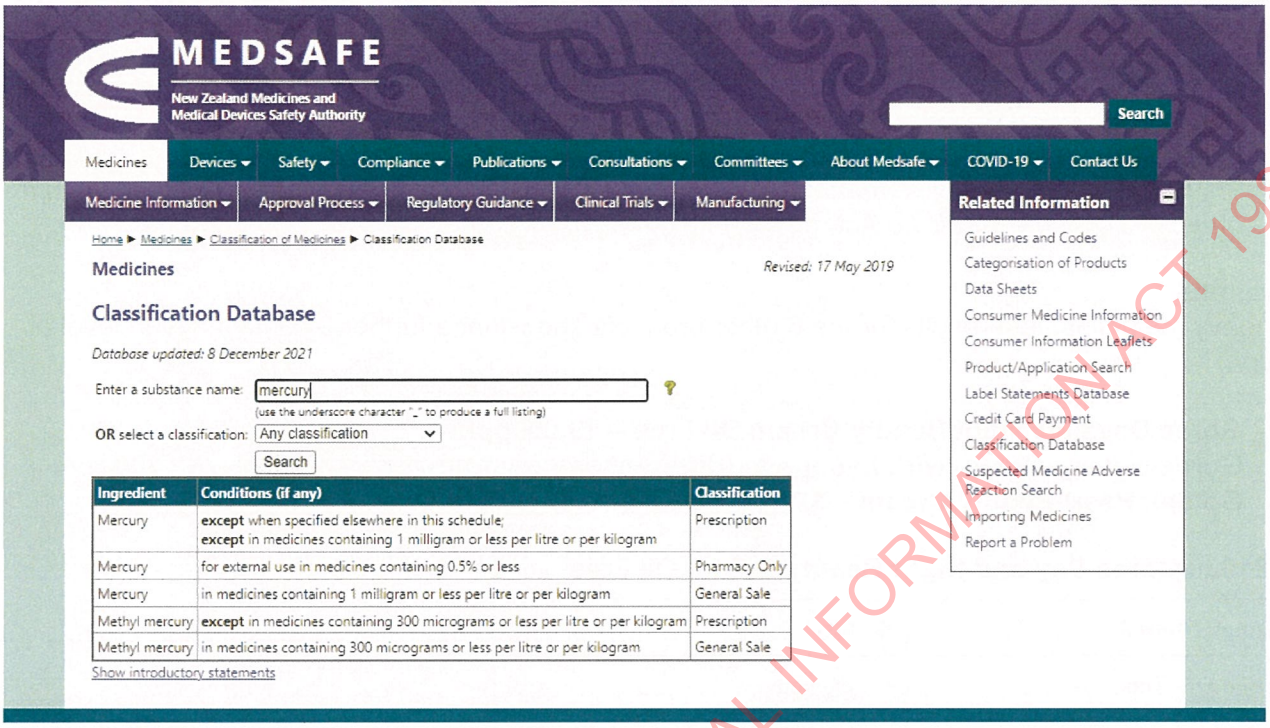
> *…is the only cream that clear pimples, wrinkles, marks, hives, even shadows under the eyes and turns your skin white …*
>
> *Although the … cream is the best skin whitening cream formulation, yet we are in a process to make it even better by way of collecting precious herbs and extracting their ingredients and then treating and developing them … removes the prominent pimples, cists, gloom and other acne problems. It protects the face from the after effects of the sunlight, harsh and allergic conditions following regular makeup.*

Classification

In relation to the issue of whether any of these particular products are considered medicines, we note the following:

- As we understand it, skin whitening creams work by decreasing the amount or concentration of melanin in skin cells.
- Mercury was used as mercurous chloride, oxide and ammoniated mercury in many cosmetics and toiletries in the early part of the 20th century before it was realised it caused toxicity. Long term application of mercurial products to the skin makes the skin and nails darker because the mercury is deposited in the epidermis, hair, follicles, and dermis.

- Mercury is still found in some skin lightening creams because it inhibits the enzyme (tyrosinase) that leads to melanin production[1] (rather than it being an excipient or by-product contaminant) and this could arguably be considered a therapeutic purpose and effect per s4.
- These products (containing mercury) would not meet cosmetic products groups standards.
- Mercury is currently scheduled in the Medicines Regulations 1984 as follows:



Cosmetics
The following information regarding cosmetics can be found at the following Medsafe link:
http://www.medsafe.govt.nz/regulatory/regguidance.asp#Cosmetics

> *A cosmetic is a product used to cleanse, protect or beautify the hair or skin. Cosmetics must not have a therapeutic purpose or contain a scheduled ingredient.*
>
> *A product marketed as a cosmetic must comply with the **Cosmetic Products Group Standard**, which is published by the Environmental Protection Authority. Regulations 24 and 26-36 of the Medicines Regulations 1984 also have requirements that apply to cosmetics.*
>
> *There is no approval or registration process in New Zealand for cosmetics that meet these requirements. It remains the responsibility of the sponsor (ie, you) to ensure the cosmetic is made to an acceptable quality and is safe to use.*
>
> *View Part 1 of the Guideline on the Regulation of Therapeutic Products in New Zealand for further guidance on cosmetics, or contact the Environmental Protection Agency for further advice.*

See:

https://www.epa.govt.nz/industry-areas/hazardous-substances/guidance-for-importers-and-manufacturers/cosmetics/

https://www.epa.govt.nz/assets/RecordsAPI/Cosmetic-Products-Group-Standard-2020-HSR002552.pdf

[1] See: https://onlinelibrary.wiley.com/doi/full/10.1111/j.1468-2494.2010.00616.x

https://www.epa.govt.nz/assets/RecordsAPI/Cosmetic-Products-Group-Standard-Schedules-4-8-HSR002552.pdf

Schedule 4 of the Cosmetic Products Group Standard Additional Standards details components that cosmetic products must not contain – mercury and its compounds is listed at reference 221.[2]

EPA input
I have been advised that:

> "…*the group standard states*: *This Group Standard does not cover registered medicines under the Medicines Act 1981 or products intended for the treatment of medical conditions as defined under the Medicines Act 1981 where registration is required.*
>
> *Therefore, if the product is marketed claiming it is a treatment of any medical conditions, then it may fall under the Medicine Act, and will be exempted from HSNO."*

ESR results
ESR heavy metal final test results for the 6 other products show that a further 2 contain a high level of mercury:

- **Goree Day and Night Beauty Cream Oil Free – 19,000ppm**
- **Goree Beauty Cream with Lycopene (different sample to that first tested) – 22,300ppm**
- **Golden Pearl Beauty Cream – 12,200ppm**

CAP 21029 Goree Day and Night Beauty Cream Oil Free

Parameter tested	Results
Aluminium - Total*	< 5000 ppm
Arsenic - Total*	< 50.0 ppm
Copper - Total*	< 300 ppm
Iron - Total*	< 3000 ppm
Lead - Total*	10200 ppm
Manganese - Total*	< 100 ppm
Mercury - Total*	19000 ppm
Zinc - Total*	< 10000 ppm

[2] Except special cases listed in Schedule 7.

CAP 21030 Goree Beauty Cream with Lycopene (retested)

Parameter tested	Results
Aluminium - Total*	< 5000 ppm
Arsenic - Total*	< 50.0 ppm
Copper - Total*	< 300 ppm
Iron - Total*	< 3000 ppm
Lead - Total*	12200 ppm
Manganese - Total*	< 100 ppm
Mercury - Total*	22300 ppm
Zinc - Total*	< 10000 ppm

CAP21032 Golden Pearl Beauty Cream

Parameter tested	Results
Aluminium - Total*	< 5000 ppm
Arsenic - Total*	< 50.0 ppm
Copper - Total*	< 300 ppm
Iron - Total*	< 3000 ppm
Lead - Total*	17200 ppm
Manganese - Total*	< 100 ppm
Mercury - Total*	12200 ppm
Zinc - Total*	35400 ppm

Also:

All 3 products of concern labelling indicate they are made in Pakistan.

Environmental and Border Health (MOH) input

I have been directed to the MOH publication, *The Environmental Case Management of Mercury-Exposed Persons (July 2021), which* includes the following:

> **2.3.1 Mercury in skin-lightening preparations**
>
> Skin-lightening products may take the form of creams, milks, oils, ointments or soaps. The terms 'skin-lightening', 'skin-bleaching' and 'skin-whitening' are all used to describe such products.
>
> These products may contain a range of active ingredients, including mercury, hydroquinone, topical corticosteroids (TCs), hydrogen peroxide, kojic acid, arbutin, nicotinamide, tretinoin, azelaic acid, salicylic acid, phenols and solvents. Mercury inhibits production of the skin pigment melanin in epidermal melanocytes by inactivating sulfhydryl mercaptan enzymes, leading to inactivation of tyrosinase, an important catalyst in melanin production.
>
> Skin-lightening products have a legitimate dermatologic role in the treatment of hyperpigmentation disorders, such as melasma and post-inflammatory hyperpigmentation. However, such products are also commonly used in a number of African, Asian and Latin American countries and amongst dark-skinned populations in North America and Europe to produce a general cosmetic lightening of the skin. Mercury may be present in skin-lightening products as ammoniated mercury, mercury iodide, mercurous chloride, mercurous oxide or mercuric chloride.
>
> Products have been reported to contain mercury at concentrations as high as 30 percent, although concentrations in the range of 1–6 percent are more common (Cressey 2014). While the route of exposure will be principally dermal, following direct application of the skin-lightening product, furniture, bedding and surfaces in the user's dwelling can become highly contaminated, and a study of households of women using skinlightening products found elevated urinary mercury concentrations in some non-users in the same household (Copan et al 2012).
>
> It was uncertain what the exposure route was for these non-users, but it was likely to include dermal and oral exposure. The limited amount of information available on dermal absorption of mercury from skin-lightening products suggests that 1–4 percent of the applied dose may be absorbed. It is unknown how common the use of skin-lightening products is in New Zealand.

I have also been advised that there may be a breach of the Minimata convention[3] which aims at banning the trade of mercury containing products, so this issue may be something that the Ministry for the Environment will be interested in as well.

Next steps

As there are public health concerns regarding these products, which we consider are subject to the Medicines Act (due to the mode of action of the mercury as described above), it is recommended that a s98 safety communication statement is made for the purposes of protecting the public. If agreed, a statement can be released to the media so that the issue can become widely known. Information will also be published on the Medsafe website.

If further product is discovered, IET staff can exercise their statutory powers under the Medicines Act to detain and/or seize product.

However, Medsafe will also make contact with the Ministry for the Environment (potentially Andy Morgan, Policy Analyst, and Mariska Wouters, Comms) regarding whether it wishes to issue a similar statement or message to the public around the same time as Medsafe.

Medsafe will also notify the EPA and the Ministry for the Environment of the proposed Medsafe action to be taken regarding these products.

Action

Please consider this action and the attached draft s98 communication and DG memo.

Scott Read
Senior Investigator
Investigation and Enforcement
Compliance Management
Medsafe
Health System Improvement and Innovation
Ministry of Health

[3] https://www.mercuryconvention.org/en

Memo

Date:	22 21 December 2021
To:	Sarah Turner, Acting Director-General of Health
Copy to:	Emma Prestidge, Acting Deputy Director-General, Health System Improvement & Innovation
From:	Chris James, Group Manager, Medsafe
Subject:	Issue of a Privileged Statement pursuant to section 98 of the Medicines Act 1981 to warn the public about the presentation of skin whitening cream products that contain undeclared mercury
For your:	Decision

Summary

The purpose of this memo is to:

- Brief you about an ongoing enforcement investigation into the supply of a presentation of skin whitening products found to contain undeclared mercury and lead.
- Request that you approve the release of a qualified privileged statement under section 98 of the Medicines Act 1981 (attached) in order to warn the public about the risk to health posed by these products.
- Advise that the Ministry for the Environment supports the publication of this statement.

Background

Medsafe was alerted to the presence of these products in the New Zealand market by the Bay of Plenty DHB Public Health Unit (DHB PHU), after a local GP had reported a case of potential mercury poisoning of a patient. Information gathered by the DHB found that the patient had used the product *Goree Beauty Cream with Lycopene*.

An overseas regulator has previously generated an alert that this product is adulterated with mercury.

Medsafe arranged for the remainder of the product used by the patient to be sent by the DHB PHU directly to the Institute of Environmental Science and Research (ESR) for testing. The product was found to contain mercury at a high level. Mercury is included in Schedule 1 of the Medicines Regulations 1984, and at the levels found, the product would be a prescription medicine.

In addition, the Medsafe Investigation and Enforcement Team (IET) has located other similar products of interest and has detained them, in order to have them laboratory tested for the presence of heavy metals by the ESR. A further two products were identified as containing high levels of mercury.

Medsafe staff have seized the product from the business identified by the patient.

Medsafe considers that these products are medicines based on the intended purpose of the products and the mode of action by which this purpose is achieved.

Confirmation has been received from the Environmental Protection Agency (EPA) that mercury is not permitted to be included in cosmetics, except in certain limited circumstances. Any regulatory action

required in regard to cosmetics is done through the Environmental and Border Health group within the Ministry of Health, and Sally Gilbert, Manager of this group has been consulted.

The Ministry for the Environment (MfE) has been informed. The presence of these mercury containing products in New Zealand has been discussed with representatives from MfE and support for the proposed Privileged Statement has been given.

As there are public health concerns regarding these products it is recommended that a qualified privileged statement is made pursuant to section 98 of the Medicines Act 1981. Such a statement is privileged and is made for the purposes of protecting the public.

If you agree, a qualified privileged statement will be released to the media so that the issue can be made widely known. A copy of the qualified privileged statement will also be published on the Medsafe website as an Alert.

Section 98 of the Medicines Act provides:

> 98 Statement by Director-General
>
> (1) The Director-General may, for the purpose of protecting the public, publish statements relating to medicines of any description or medical devices of any kind or to any matter contained or implied in advertisements, either generally or in any particular advertisement, or any class or classes of advertisements, relating to medicines of any description or medical devices of any kind.
>
> (2) Every statement published under this section shall be protected by qualified privilege.

Action

If you approve the release of the attached qualified privileged statement under section 98 of the Medicines Act 1981, please append your signature below.

Recommendations

It is recommended that you:

1.	agree	To the release of the attached qualified privileged statement under section 98 of the Medicines Act 1981	Yes/No

Signature _____ Date: 22 December 2021
Chris James
Group Manager, Medsafe

Signature _____ Date: 22 · 12 · 21
Sarah Turner
Acting Director-General of Health