IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY **CIV 2014-485-4138**

UNDER	**the Judicature Amendment Act 1972 and the Declaratory Judgments Act 1908**
IN THE MATTER	**of an application for judicial review and an application for a declaration**
BETWEEN	**NEW HEALTH NEW ZEALAND INC**
	Plaintiff
AND	**ATTORNEY-GENERAL for and on behalf of the Minister of Health**
	Defendant

PLAINTIFF'S SYNOPSIS OF SUBMISSIONS

Dated 18 September 2014

Hearing: Thursday 2 October 2014, 10 am

Solicitor
Wynn Williams Lawyers
Homebase
Unit B 195 Marshland Road
Shirley
P O Box 4341
Christchurch
Ph: (03) 379 7622
Fax: (03) 353 0247
Solicitor: Jonathan Gillard

Counsel:
Lisa Hansen
Level 8, Wakefield House
90 The Terrace
PO Box 8045
Wellington 6143
Ph: 914 1052
Fax: (04) 473 3179
Email: l.hansen@barristerscomm.com

INTRODUCTION

What this case is about

1. The plaintiff says that the chemicals used in water fluoridation are medicines under the Medicines Act 1981. It says that the Ministry of Health must take steps to ensure that the manufacture, sale supply and distribution of these chemicals comply with the relevant requirements of the Medicines Act.

Setting the scene

2. Some local authorities in New Zealand add fluoride-releasing salts to their water supplies to a concentration of between 0.7 and 1 part per million (ppm) fluoride.

3. This process of artificially increasing the fluoride concentration in the water supply is known as community water fluoridation (CWF).

4. The fluoride compounds purchased by local authorities and used in CWF are primarily hydrofluosilicic acid (HFA) and sodium silicofluoride (SSF).

5. HFA is a by-product of the manufacture of phosphate fertilisers. Phosphate rock, which contains fluoride and silica, is treated with sulphuric acid. This produces two gases: silicon tetrafluoride and hydrogen fluoride. These gases are passed through scrubbers where they react with water to form hydrofluosilicic acid. In its concentrated form, it is a poison and classified as a hazardous substance.

6. SSF is generally produced from the addition of sodium carbonate or sodium chloride to HFA.

7. SSF and HFA typically contain heavy metal contaminants including arsenic, a known carcinogen, mercury and lead.

8. The claimed purpose of adding HFA and SSF to water supplies is to reduce the incidence of tooth decay.

9. Tooth decay, or dental caries, is a multifactorial disease in which bacteria (especially *streptococcus mutans* and related species) metabolize dietary sugars and produce lactic acid. A local acidic environment promotes caries by dissolving tooth enamel. Individuals with significant numbers of oral *mutans* bacteria are at increased risk of caries, especially with repeated consumption of sugary food and beverages, and in the absence of good dental hygiene.[1]

10. The action of fluoride ions, in sufficient concentration is thought to retard demineralisation and promote the mineralisation of tooth enamel and thereby protect against dental caries.[2] Fluoride operates topically on tooth surfaces. Its purpose and effect is to prevent dental decay.

11. Under the Medicines Act 1981 a medicine is defined as a substance that is manufactured, sold or supplied wholly or principally for administering to a human being for a therapeutic purpose and which achieves its intended action on the human body by pharmacological means.

12. A therapeutic purpose includes preventing and treating disease.

13. HFA and SSF when used in CWF have these essential characteristics of medicines. Their use is intended to cause a pharmacological effect (mineralisation of tooth enamel via the release of fluoride ions), and they are used in one or more human beings primarily for a therapeutic purpose, namely the prevention of the disease dental decay.[3]

14. The plaintiff says that HFA and SSF are consequently medicines under the Medicines Act 1981 and are subject to the regulatory controls of that

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[1] Menkes first affidavit paragraph [12]

[2] Menkes first affidavit paragraph [11]

[3] Menkes first affidavit, paragraph [29] and second affidavit paragraph [7]

Act. In particular, they cannot be used as a medicine unless approved by the Minister of Health and the manufacturer is issued with a licence. The following declarations are sought:

14.1. A declaration that when sold to and supplied or distributed by local authorities for the purpose of CWF, HFA and SSF are medicines under the Medicines Act.

14.2. A declaration that the Ministry of Health is required to take all necessary steps to ensure that the manufacture, distribution, sale and supply of HFA and SSF complies with the Medicines Act and regulations.

Key issues

15. The key issues are:

15.1. Are HFA and SSF medicines under the Medicines Act?

15.2. What are the legal consequences under the Medicines Act of HFA and SSF being recognised as medicines.

THE PLEADINGS AND THE EVIDENCE

Background to the claim

16. The genesis of this proceeding is a decision of Rodney Hansen J in *New Health NZ Inc v South Taranaki District Council* [2014] NZHC 395 (which is under appeal).

17. In 2013 the plaintiff issued a judicial review proceeding against the South Taranaki District Council challenging its decision to add fluoride to the Patea and Waverley water supplies.

18. The challenge included the following grounds:

18.1. There was no legal power to add fluoride.

18.2. If there was power, its exercise by the Council was a breach of the right to refuse medical treatment in s 11 of NZBORA.

19. The judge rejected the plaintiff's claim. On the first ground the judge concluded:

19.1. There is implied power to fluoridate in the LGA 2002. In coming to that conclusion he relied on s 130 of the Local Government Act, the definition of "water supply", the fact an implied power was present in the antecedent legislation (the Municipal Corporations Act 1954 and the LGA 1974), and that the Health Act confirms that fluoride may be added to drinking water in accordance with drinking water standards issued under that Act;

19.2. The power to fluoridate drinking water is not a regulatory function and does not require express authority;

19.3. Water is not a food for the purposes of the Medicines Act.

20. On whether fluoridation is medical treatment under s 11 of the NZBORA Rodney Hansen J held:

20.1. Fluoridation of water is not medical treatment for the purpose of s 11 of NZBORA. Although he found that fluoridation has a therapeutic medical purpose, he concluded that the means by which the purpose is effected does not constitute medical treatment. He said that medical treatment is confined to direct interference with the body or state of mind of an individual and does not extend to public health interventions delivered to the inhabitants of a particular locality or the population at large. He saw no material distinction between fluoridation and other

established public health measures such as chlorination of water or the addition of iodine to salt.

20.2. If he was wrong about fluoridation not being medical treatment, he concluded that it is prescribed by law and that the power to fluoridate is a justified curtailment of the right to refuse medical treatment. He said that the evidence relied on by the Council shows that the advantages of fluoridation significantly outweigh the mild fluorosis which is an accepted outcome of fluoridation.

21. This judgment is under appeal and is expected to be heard in early 2015.

22. The judge made a particular finding that is relevant to this case, namely that

> fluoridation has a therapeutic medical purpose, preventing tooth decay, and a known pharmacological effect, namely the mineralisation of tooth enamel: paragraph [58]

23. The plaintiff says that a necessary consequence of this finding is that HFA and SSF are medicines under the Medicines Act.

24. The plaintiff through counsel wrote to the Ministry of Health expressing its view of the Medicines Act ramifications of the judge's findings. The Ministry of Health refused to accept that it had the effect contended for by the plaintiff: refer third Sloan affidavit dated 28 July 2014, paragraphs [42] to [45] and appendix J.

25. Because the Ministry is refusing to do its job, the plaintiff has been obliged to bring this proceeding.

The pleadings

26. The statement of claim alleges that HFA and SSF are medicines and seeks a declaration to that effect.

27. The statement of claim also asserts that HFA and SSF require the consent of the Minister of Health and the manufacturer requires a licence and declarations are sought to that effect.

28. The plaintiff now says that the appropriate declaratory relief would be that the Ministry of Health is required to take all necessary steps to ensure that the manufacture, distribution, sale and supply of HFA and SSF complies with the Medicines Act and regulations.

The evidence

29. The plaintiff has filed two affidavits from David Menkes and three affidavits from David Sloan.

30. Dr Menkes is an expert witness providing an opinion on whether HFA and SSF are medicines. His unequivocal opinion is that they are.

31. The evidence of Mr Sloan addresses the merits of fluoridation. While this is not directly in issue, the defendant has asserted that fluoridation is safe and effective. The plaintiff does not accept that the evidence responsibly interpreted supports the proposition that fluoridation is safe and effective and has supplied a selection of the substantial body of scientific evidence against fluoridation.

OVERVIEW OF THE MEDICINES ACT 1981

32. The Medicines Act came into force in August 1984 and was consolidating legislation supplanting the Food and Drug Act 1969. The Act, together with any regulations made under it, are administered by the Ministry of Health.

33. According to its long title it is:

> An Act to consolidate and amend the law relating to the manufacture, sale and supply of medicines, medical devices and related products.

34. A broad objective is to ensure that medicines and products used in New Zealand are safe and effective.

35. The Act has been described as public welfare legislation designed to protect the public from potential health risks in relation to claims made regarding the therapeutic benefits of products that have not had appropriate clinical trials and testing.[4]

36. The Act sets out controls on the manufacture, supply and advertising (promotion) of medicines and also defines the term "medicine". Apart from a few limited circumstances that are set out in the Medicines Act, medicines cannot be advertised, sold or distributed unless they have first been approved by the Minister of Health.

37. There are four classifications of medicines:[5]

    37.1. Prescription medicines – can only be sold supplied or administered under a prescription by a person authorised to prescribe medicines, eg medical practitioner, dentist, registered midwife, veterinarian, a designated prescriber;

    37.2. Restricted medicines – a medicine which can only be sold or supplied by a pharmacist from a pharmacy or hospital or in accordance with a standing order;

    37.3. Pharmacy-only medicines – a medicine which can be sold or supplied from a pharmacy or hospital or shop license to sell specific medicine;

    37.4. General sale medicines – these are not scheduled or classified and may be supplied from any retail outlet.

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[4] *Ministry of Health v Pacific Pharmaceuticals Ltd* (High Court, Auckland A 165/00, 16 February 2001, paragraph [19]

[5] It should be noted that a listing of a particular substance in the First Schedule of the Medicines Act does not necessarily mean that it is currently approved for distribution in new Zealand, but rather, that it would be classified as indicated if it was approved for distribution.

38. Fluoride in various preparations fits within each of these classifications: refer Medicines Regulations 1984 and paragraph 16 and Exhibit D of David Sloan's third affidavit dated 28 July 2014.

39. The approval process for medicines involves an application comprising information about the safety, efficacy and quality of the ingredients and the final product, accompanied by an appropriate fee. This is followed by an evaluation of the information after which the Minister of Health may approve the product by notifying consent in the New Zealand *Gazette*.

40. Some narcotic and psychotropic products that are used for therapeutic purposes are classified as controlled drugs. These products are regulated under both the Medicines Act and the Misuse of Drugs Act 1975.

41. Similarly, products that are medicines that contain hazardous substances or new organisms are subject to both the Medicines Act and Hazardous Substances and New Organisms Act 1996 (HSNO Act). In certain cases parallel approvals under both Acts will need to be obtained.

42. Medsafe (the New Zealand Medicines and Medical Devices Safety Authority) operates as a business unit within the Ministry of Health. Medsafe is responsible for administering most aspects of the Medicines Act 1981 and its associated regulations in New Zealand including:

    42.1. approval of new and changed medicines and related products

    42.2. audit and licensing of medicine manufacturers;

    42.3. approval of clinical trials of new medicines;

    42.4. classification of medicines;

    42.5. pharmacovigilance;

    42.6. surveillance and monitoring;

    42.7. border control and enforcement;

42.8. administration of a database of medical devices in New Zealand;

42.9. oversight of medicine and medical device recalls.

Types of therapeutic products controlled under the Medicines Act[6]

43. The Medicines Act controls products used in humans for a therapeutic purpose. Products used for therapeutic purpose can be categorised as medicines, related products, herbal remedies or medical devices.

44. In practical terms a product is a medicine if it is administered to humans primarily for a therapeutic purpose and has a pharmacological effect. A medicine excludes: a medical device, food under the Food Act 1981, radioactive material within the meaning of s 2(1) of the Radiation Protection Act 1965, animal food or medicine, animal remedy or any substance or article of a kind or belonging to a class that is declared by regulations not to be a medicine. Except in limited circumstances Ministerial consent is required to the distribution of a medicine.

45. Related products are primarily a food, dentifrice or cosmetic that has secondary therapeutic use. This term is defined in s 94 and the consent of the Minister is required before a new related product can be legally distributed in New Zealand.

46. A herbal remedy is a special sub-category of medicine defined in s 2 of the Medicines Act. A herbal remedy is a medicine that does not contain a prescription, restricted or pharmacy-only medicine, and consists of a substance derived from plant material that has been dried or crushed (or derived through any other similar process). It may also be an aqueous or alcoholic extract of the dried or crushed palnt material, or a mixture of that material with another inert substance. In general terms Ministerial

[6] New Zealand Regulatory Guidelines for Medicines: Part A when is an application for approval of a new or changed medicine required", Edition 6.15, November 2011.

consent is only required if the herbal remedy is sold with a recommendation for use for a therapeutic purpose.

47. A medical device is any device, instrument, apparatus etc used primarily for use in humans for a therapeutic purpose but does not achieve its principal intended action by pharmacological means. It includes bandages and surgical dressing provided they are not medicated with a therapeutic agent. If medicated they are medicines. Ministerial consent is not required to the distribution of medical devices. However medical devices are subject to the notification requirements set out in the Medicines (Database of medical Devices) Regulations 2003.

48. Two other categories of products should also be mentioned.

49. A cosmetic is defined in s 2 of the Medicines Act as a substance used for the purpose of beautifying, improving, protecting or cleansing hair, skin and complexion and includes perfume, deodorant, insect repellent and dusting powder. Provided a cosmetic does not claim to have a therapeutic purpose Ministerial consent is not required for its distribution.

50. Dietary supplements are controlled under the Dietary Supplement Regulations 1985. In practical terms, a dietary supplement is an edible substance, in a controlled dosage form which is intended to supplement the intake of substances normally derived from food. A product marketed as a dietary supplement cannot be promoted for a therapeutic purpose. Otherwise it requires consent under the Medicines Act as a medicine or related product.

How is fluoride treated under the Medicines Act?

51. As noted above, fluoride in various preparations has been classified as a restricted medicine, prescription and pharmacy-only medicine, and general medicine.

52. Sodium-fluoride tablets for example, are a pharmacy only medicine.

53. Non-liquid products for external use containing more than 1500 parts per million of fluoride are restricted medicines.

54. Fluoride mouthwashes that are also intended to be swallowed as a supplement are medicines.[7]

55. Regulation 58A(1)(a) of the Medicines Regulations 1984 declares that dentifrice products not containing a medicine or used in relation to any therapeutic purpose other than to prevent dental decay and/or improve oral hygiene are not medicines or related products for the purposes of the Medicines Act.

56. A dentifrice is defined in s 2 of the Medicines Act as any substance or mixture used or represented for the use or purpose of cleansing the mouth or teeth.

57. This regulation means that fluoride toothpaste at 1000 parts per million for example is not a medicine.

58. In summary, a substance containing fluoride that is used to treat dental decay is considered to be a medicine, unless exempted under Regulations.

KEY DEFINITIONS IN THE MEDICINES ACT

59. The definition of "medicine" was amended on 1 July 2014 to read as follows:

> 3(1) In this Act, unless the context otherwise requires, **medicine**—
>
> (a) means any substance or article that—
>
> (i) is manufactured, imported, sold, or supplied wholly or principally for administering to 1 or more human beings for a therapeutic purpose; and
>
> (ii) achieves, or is likely to achieve, its principal intended action in or on the human body by pharmacological, immunological, or metabolic means; and

[7] Ibid p 2

(b) includes any substance or article—

(i) that is manufactured, imported, sold, or supplied wholly or principally for use as a therapeutically active ingredient in the preparation of any substance or article that falls within paragraph (a); or

(ii) of a kind or belonging to a class that is declared by regulations to be a medicine for the purposes of this Act; but

(c) does not include—

(i) a medical device; or

(ii) any food within the meaning of section 2 of the Food Act 1981; or

(iii) any radioactive material within the meaning of section 2(1) of the Radiation Protection Act 1965; or

(iv) any animal food in which a medicine (within the meaning of paragraph (a) or (b)) is incorporated; or

(v) any animal remedy; or

(vi) any substance or article of a kind or belonging to a class that is declared by regulations not to be a medicine for the purposes of this Act.

60. For the purposes of this claim, the focus is on subparagraph (1). It is not in dispute that the exclusions in subparagraph (c) do not apply.

61. The previous definition is contained in Appendix A. The principal changes include:

61.1. a new subparagraph (a)(ii);

61.2. the express exclusion of food from being a medicine.

62. The definition of "administer" in s 2 provides:

Administer means administer to a human being, either—

(a) Orally or by injection or by introduction into the body in any other way; or

(b) By external application, whether by direct contact with the body or not;—

and every reference in this Act to administering a substance or

> article is a reference to administering it either in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, some substance in which it is to be administered:

63. "Substance" is defined in s 2 as "any natural or artificial substance, whether in solid or liquid form or in the form of a gas or vapour".

64. "Manufacture" in relation to a medicine includes any process carried out in the course of making the medicine but does not include dissolving or dispersing the medicine in, or diluting or mixing it with, some other substance used as a medium for the purpose of administering the medicine to a particular person: s 2.

65. "Therapeutic purpose" (was also amended on 1 July 2014) is defined in s 4 (refer Appendix A for previous definition):

> **4 Meaning of therapeutic purpose**
>
> In this Act, unless the context otherwise requires, **therapeutic purpose** means any of the following purposes, or a purpose in connection with any of the following purposes:
>
> (a) preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect, or injury; or
>
> (b) influencing, inhibiting, or modifying a physiological process; or
>
> (c) testing the susceptibility of persons to a disease or ailment; or
>
> (d) influencing, controlling, or preventing conception; or
>
> (e) testing for pregnancy; or
>
> (f) investigating, replacing, or modifying parts of the human anatomy.

FIRST ISSUE: ARE HFA AND SSF MEDICINES?

66. A medicine has two principal features.

67. First, it must be a substance that is manufactured, sold or supplied wholly or principally for administering to one or more human beings for a therapeutic purpose. Secondly, it must be a substance that achieves or is

likely to achieve its principal intended action on the human body by pharmacological, immunological, or metabolic means.

68. HFA and SSF easily satisfy both limbs. First, HFA and SSF are each a:

68.1. (artificial) substance

68.2. "manufactured", "sold", and "supplied" wholly or principally

68.3. for the purpose of being introduced orally into the human body via dilution through the public drinking water supply (ie to administer to human beings)

68.4. for the therapeutic purpose of preventing and treating the disease of dental decay.

69. HFA and SSF are manufactured for, sold to, and supplied by Councils for CWF. CWF has an exclusively therapeutic purpose in that it is for the purpose of preventing the disease of dental decay. The intention is that the fluoride will be mixed with water and ingested orally by the population when they drink or consume foods prepared with communal water supplies.

70. It is not in dispute that dental decay is a disease. For completeness it is noted that dental decay is listed in part 2 of Schedule 1 of the Medicines Act as a particular class of disease or physiological condition: s 58(1)(b).

71. Secondly, HFA and SSF achieve their principal intended action on the human body by pharmacological means.

72. In unchallenged expert evidence Dr David Menkes says in his first affidavit that HFA and SSF are being used as medicines. In respect of the mechanism of action on the human body he says:

> [21] It is my opinion that HFA or SSF are used to achieve their principal intended action by increasing the concentration of fluoride ions, thus affecting mineralisation of tooth enamel and thereby preventing dental caries. This action on the human body

> is achieved by pharmacological means and thus satisfies the requirements of the revised definition of a medicine described in paragraph 19.
>
> [22] The caries-preventive action of fluoride is mainly topical in that fluoride ions in sufficient concentration interact with the surface of the tooth enamel and can thereby inhibit demineralisation and promote remineralisation.

73. Dr Menkes also says that as well as intended to prevent disease, the fluoride-releasing compounds HFA and SSF when used in CWF could also be said to come within subparagraph (b) of the definition of "therapeutic purpose", in that they are used for the purpose of influencing, inhibiting, or modifying a physiological process (refer paragraph [23] of his first affidavit).

74. HFA and SSF when used in water fluoridation have other characteristics of a medicine, namely a dose-response relationship. This is explained by Dr Menkes in paragraph 24 of his first affidavit.

> [24] As used in New Zealand, CWF also can be seen to have a further characteristic of the use of medicines, namely the dose-response relationship. The current target range of 0.7 – 1.0 ppm fluoride in tap water, achieved by the careful addition of HFA or SSF to communal water supplies, is based on the Ministry's view that this range offers the optimum balance between desired effects and unintended adverse or toxic side-effects. Regular monitoring is required to ensure that the concentration of fluoride ions in tap water stays within this target range. Lower levels are less likely to be effective, while higher levels are more prone to produce adverse effects. In other words, the 0.7 to 1.0 ppm concentration range has been specifically chosen to achieve an optimum dose-response for this intervention.

75. Fluoride in various preparations is classified variously as a general medicine, pharmacy-only, prescription and restricted medicine.

76. HFA and SSF are used for the same therapeutic purpose and have the same pharmacological mechanism of action as a recognised pharmacy-only medicine, namely sodium fluoride.

77. Ingesting two 1.1 mg sodium fluoride tablets supplies a person with approximately 1.0 mg of elemental fluoride, the same dose as obtained by consuming 1 litre of water fluoridated with HFA or SSF (at the upper target concentration of 1.0 ppm) or 1.43 litres of water fluoridated with to the lower target of 0.7 ppm.

78. As Dr Menkes says in his first affidavit:

> [27] In my opinion there is no valid medical or pharmacological reason why the delivery of the same dose of the active principle fluoride should be considered to reflect use of a medicine in one form (sodium fluoride tablets) and not in the other (water fluoridated with HFA or SSF), particularly when, as in the example given in paragraph 26, both reflect a typical daily dose and are supplied by a fluoride-releasing salt with the same therapeutic purpose.
>
> [28] There is thus no essential difference, in therapeutic intent or pharmacological mechanism, between ingesting the same dose of fluoride by tablet or by fluoridated water. Both can be said to reflect the use of medicine, particularly in light of the fact sodium fluoride tablets should, according to Ministry guidelines, be "chewed or sucked, or dissolved in drinking liquid".[8]

79. The Crown does not appear to contest the evidence adduced by the plaintiff that HFA and SSF have a therapeutic purpose and a pharmacological mechanism of action. This is understandable in light of the findings of Rodney Hansen J in *New Health NZ Inc v South Taranaki District Council* (paragraph [58]).

80. Rather their arguments, to the extent they can be discerned from the evidence of Dr Jessamine and the statement of defence, include:

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[8] www.health.govt.nz/system/files/documents/publications/guidelines-for-the-use-of-fluoride-nov09.pdf

80.1. Medsafe has never considered either water with added fluoride or the fluoridating chemicals to be a medicine.

80.2. A substance is a medicine when in dose form intended for direct human consumption for a therapeutic purpose. Because HFA and SSF are sold in industrial size containers and not in recognisable dose forms and are not directly consumed in undiluted form, they can't be medicines.

80.3. A pragmatic filter is required to be applied to the legislation because otherwise water and oxygen and chlorine could be considered medicines.

80.4. The presence of a chemical that is scheduled as a medicine under the Medicines Act is insufficient to lead to a conclusion that a product has medicinal qualities or that it is a medicine. The example of lithium in a lithium battery or in paint.

80.5. That HFA and SSF are regulated exclusively by the Hazardous Substances and New Organisms Act.

80.6. The safety and quality of water supplies are regulated by the Health Act.

81. Each of these points is disputed and is addressed below.

First point: Medsafe has never considered fluoridated water or fluoridating chemicals to be a medicine

82. It is accepted that water per se is not a medicine. However, that is not the point. The point is that water is being used to deliver a pharmacologically active substance with a therapeutic purpose to one or more human beings.

83. As Dr Menkes observes in his second affidavit, medicines are often delivered through an aqueous solution. For example acutely dehydrated or hypotensive patients treated with intravenous saline in emergency

settings often also receive specific medicines dissolved in the saline (such as chlorpromazine for severe migraine with vomiting, or adrenaline for anaphylactic shock). In these cases the principal purpose of the saline infusion is hydration, but the added medicines also have a specific therapeutic purposes, and their classification and use as medicines is in no way diminished by the fact that they are administered in an aqueous solution given for another primary purpose.[9]

Second point: that a substance is a medicine when in dose form and intended for direct human consumption

84. This point would require the defendant to rewrite the definition of a medicine. There is no reference to a medicine being defined by a requirement to be in a dose form per se or a requirement that it be able to be delivered in an undiluted form.

85. Dr Jessamine may be referring to the definition of dietary supplement which does refer to dose form and contemplates being ingested in an undiluted form.

> **[2A Meaning of dietary supplement**
>
> (1) In these regulations, **dietary supplement** means something to which subclauses (2)to(6) apply.
>
> (2) It is an amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin.
>
> (3) It is sold by itself or in a mixture.
>
> (4) It is sold in a controlled dosage form as a liquid, powder, or tablet (which might be described on the label as a cachet, capsule, lozenge, or pastille instead of as a tablet).
>
> (5) It is intended to be ingested orally.
>
> (6) It is intended to supplement the amount of the amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin normally derived from food.]

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[9] Second Menkes affidavit, paragraph [18]

86. In any event Dr Menkes' second affidavit comprehensively rebuts these points. A substance can be a medicine even if not in a recognised dose form or delivered directly for human consumption:

> [28] Dr Jessamine also says at paragraph 33 that such industrial size containers are not "recognisable medicinal dose forms". This characteristic also applies to nitrous oxide, but this in no way diminishes its use or status as a medicine.
>
> [29] The size or shape of the container supplying a medicine thus does not determine its classification. What matters is how it is used, for what purpose, and whether it has a recognised pharmacological mechanism of action.
>
> [30] An essential characteristic of a medicine is dose control, in order to optimise the balance between intended and adverse effects.[10]
>
> [31] Consistent with this principle, CWF requires fluoride concentrations in the target range (0.7 – 1.0 ppm) in order to provide what is thought to be an adequate dose of fluoride to prevent tooth decay while minimising risks of harm.
>
> [32] At paragraph 34 Dr Jessamine suggests that because concentrated fluoride compounds are never directly consumed in an undiluted form by human beings they are not supplied wholly or principally for administration to a human being for a therapeutic purpose.
>
> [33] This is incorrect in my view. Many medicines require dilution before they are administered and act upon the human body. To avoid cardiac arrest, for example, potassium chloride solution (0.75 g/10 mL) **must** be diluted in an aqueous solution before intravenous injection.
>
> [34] Similarly, many chemotherapeutic drugs or volatile anaesthetics require dilution in water or air, respectively, before they can be administered safely. In each of these cases, dilution is part of normal therapeutic practice and the fact that they are supplied in a concentrated form in no way challenges their classification or use as medicines.

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[10] Richards D, Aronson J. *Oxford Handbook of Practical Drug Therapy.* Oxford University Press, 2005

Third point: pragmatic filter required

87. The notion of applying a "pragmatic filter" to the definition of "medicine" has no support in either the language of the Act or in the Parliamentary materials.

88. In the second reading of the bill on 26 August 1981 the then Minister of Health (George Gair) identified that a product would be a medicine if it made a therapeutic claim.

> Clause 3 provides that the definition of a substance as a "medicine" depends on the claims made for it, and the uses to which it is commonly put. ....If for example, a face powder is marketed for cosmetic purposes only it is neither a "medicine" nor a "related products", and in the main is outside the control of the Bill. If, subsequently it is claimed that besides improving the appearance of the face the powder also cures pimples, it becomes a related product, subject to the provisions of the Bill.

89. These statements reflected the commentary in the Explanatory Note about clause 3.

90. What Parliament contemplated and is borne out by Medsafe practise is that a product will be a medicine if it makes a therapeutic claim.

91. In Medsafe's Regulatory Guidelines the key criteria are therapeutic claim and pharmacological action.

> The medicines legislation controls products used in humans for a therapeutic purpose. Products used for a therapeutic purpose can be categorised as medicines, related products, herbal remedies or medical devices...
> A product is considered to be intended for a therapeutic purpose if a therapeutic claim is stated or implied in the product labelling or promotional material, or where the active ingredient(s) clearly has a pharmacological action. (p 1)

92. As shown in the second and third affidavits of David Sloan, Medsafe treats products that make therapeutic claims as medicines.

93. Examples include:

93.1. Advice from Medsafe that the categorisation of a product eg as a cosmetic, dietary supplement, herbal medicine, medicine etc depends on whether the ingredient/plant component has an implied therapeutic purpose and whether a therapeutic claim is being made around the use of the product: second Sloan affidavit, exhibit B.

93.2. Making a claim that lavender oil heals burns is a therapeutic claim and is not permitted: third Sloan affidavit, exhibit B.

93.3. The plaintiff also obtained from the defendant under the Official Information Act copes of various enforcement letters sent to various natural health providers. A selection of these letters is attached to these submissions.

94. In *Ministry of Health v Pacific Pharmaceuticals* (High Court, Auckland, A 165/00, 16 February 2001) the respondent claimed that lyprinol, a highly purified extract from green-lipped mussels, was beneficial in the treatment of arthritis, asthma and cancer. The respondent permitted the product to be sold in a package which contained a website reference on which therapeutic claims were made. It was prosecuted under s 20(2) of the Medicines Act for selling a medicine without the consent of the Minister and under s 58(1)(a) for advertising a medicine. The High Court on an appeal against sentence held that lyprinol was undoubtedly a medicine – "an article...that is...sold...for administering to one or more human beings for a therapeutic purpose" namely the treatment or prevention of disease.

95. The Ministry of Health itself claims that HFA and SSF prevent dental caries. If Medsafe were simply to apply its own rules to HFA and SSF it would be forced to conclude that HFA and SSF are medicines.

96. The defendant is also wrong that a pragmatic filter is required because otherwise things like oxygen, water and chlorine would be medicines.

97. Oxygen and water are essential for life and neither is manufactured, supplied etc wholly or principally for a therapeutic purpose. Chlorine similarly is not manufactured for the purpose of administering to a human being for a therapeutic purpose. It is used rather to treat water to make it potable. While this may prevent disease in a broad sense, chlorine is not administered to a person to prevent disease. A person who has a water-borne illness, for example, would not be treated with the same chlorine.

Fourth point: presence of a scheduled ingredient insufficient for substance to be medicine

98. It is correct that something that contains a scheduled ingredient may not necessarily be a medicine. A lithium-containing car battery is a good example. Such a battery does not have a therapeutic purpose or make a therapeutic claim.

99. On the other hand, certain lithium-releasing salts (eg lithium carbonate) are used as medicines to treat severe mood disorders.

100. HFA and SSF contain a scheduled ingredient, namely fluoride. The issue is whether they are being used as medicines and based on the foregoing they obviously are.

101. They are used for the same purpose (prevention of dental caries) and exert the same pharmacological effect as sodium fluoride, another fluoride-releasing salt. As Dr Menkes says in his second affidavit:

> [23] Sodium fluoride tablets (1.1 mg, each containing 0.5 mg elemental fluoride) are classified as a pharmacy-only medicine and are recommended as a substitute source of fluoride for those living in areas without CWF.
>
> [24] Based on an average consumption of 2 litres of water a day (refer paragraph 46 of Mr Prendergast's affidavit), a person in a fluoridated community ingests through the water supply a daily dose of fluoride equivalent to 3 to 4 fluoride tablets (1.5 – 2.0 mg of elemental fluoride). As indicated in the product information sheet, these tablets can be taken dissolved in water, making their administration (as well as their therapeutic

> purpose and mechanism) essentially identical to consuming water in fluoridated areas with CWF using fluoride concentrations currently recommended in New Zealand (0.7 – 1.0 mg/litre).

102. There is no meaningful distinction in therapeutic purpose or pharmacological mechanism between sodium fluoride and HFA and SSF. If sodium fluoride is a (pharmacy-only) medicine for the prevention of dental caries, HFA and SSF must also be considered medicines.

103. The Ministry appears to have a blind-spot with HFA and SSF. There is no plausible or credible reason why it has ignored regulating these as medicines when they unequivocally satisfy the criteria of a medicine. A likely explanation is that the Ministry of Health has a serious conflict of interest. It has strongly promoted water fluoridation for decades. Requiring the chemicals to comply with the Medicines Act would provide a regulatory obstacle to the promotion of that policy.

Fifth point: HFA and SSF governed by HSNO Act

104. The defendant appears to be intending to argue that HFA and SSF cannot be medicines because they are hazardous substances governed by the HSNO Act.

105. A hazardous substance is defined in the HSNO Act as follows:

> **Hazardous substance** means, unless expressly provided otherwise by regulations, any substance—
>
> (a) With one or more of the following intrinsic properties:
>
> (i) Explosiveness:
>
> (ii) Flammability:
>
> (iii) A capacity to oxidise:
>
> (iv) Corrosiveness:
>
> (v) Toxicity (including chronic toxicity):
>
> (vi) Ecotoxicity, with or without bioaccumulation; or

(b) Which on contact with air or water (other than air or water where the temperature or pressure has been artificially increased or decreased) generates a substance with any one or more of the properties specified in paragraph (a) of this definition:

106. It is understood that HFA and SSF are hazardous substances due mainly to their toxicity.

107. Medsafe's approach must be premised on the Medicines Act and the HSNO Act being mutually exclusive and that a hazardous substance cannot also be a medicine.

108. This proposition is contradicted by both the Medicines Act and the HSNO Act.

109. Section 5A of the Medicines Act says that in relation to medicines that are or contain hazardous substances or new organisms, the requirements of the Medicines Act are additional to the requirements of the HSNO Act.

110. In the event of any inconsistency between HSNO and the Medicines Act, s 110 provides that in the case of a medicine that is also a hazardous substance, the provisions of the Medicines Act prevail.

111. These provisions confirm that a medicine can also be a hazardous substance.

112. Section 24D permits the Minister to approve "in a special emergency a medicine that is or contains a hazardous substance". Under s 49B of the HSNO Act a responsible Minister may declare an adverse event to be a special emergency if the adverse event comes within that Minister's portfolio. An adverse event includes a state of emergency declared under the Civil Defence Emergency Management Act or an emergency where there is actual imminent danger to human health and safety: ss 46 and 135 HSNO Act. A declaration of a special emergency must be notified in the *Gazette* and expires of the date specified or if there is no date at the expiry of the emergency: s 49B HSNO Act.

113. The Minister of Health may approve an application with or without conditions, as long as the Minister is satisfied that the special emergency has been declared and has not come to an end, that the medicine is required for the special emergency and that an application contains the necessary information.

114. The Minister's approval of any application under s 24D must be notified in the *Gazette* and expires either on the date specified in the declaration, or the expiry of the special emergency or two years after the approval is granted: s 24F Medicines Act.

115. Section 24G provides that on the expiry of the approval the medicine to which the approval applies must not be distributed or used unless authorised by or under any other provisions of this Act.

116. There is also a separate approval regime for a medicine that is or contains a hazardous substance under ss 49C to 49K of the HSNO Act.

117. These provisions demonstrate that it is contemplated that a hazardous substance may only be used as a medicine in a special emergency.

Sixth point: Health Act

118. The plaintiff is unclear why the defendant says the Health Act might exclude the application of the Medicines Act, and reserves its position on this point until it sees the defendant's submissions.

119. Rodney Hansen J held in *New Health NZ Inc v South Taranaki District Council* that councils had an implied power to fluoridate under the Local Government Act and the Health Act.

120. This decision is under appeal in its entirety, and, unless necessary, it is not the plaintiff's intention to relitigate this finding in this proceeding.

121. While the plaintiff disputes that there is a power to add fluoride, for the purposes of this proceeding it says that the power found by Rodney Hansen J is neither inconsistent with a duty to comply with the Medicines

Act, nor does it absolve a council from complying with any other regulatory requirements such as the Medicines Act and the HSNO Act etc.

Case law supporting the plaintiff's position

122. In *McColl v Strathclyde Regional Council* 1983 SC 225 Lord Jauncey considered that the fluoride added to the water came within the definition of "medicinal product" in s 130 of the Medicines Act 1968.

123. Mrs McColl was granted legal aid to apply for an interdict to restrain the local authority from implementing a decision to fluoridate the water supply. She claimed, inter alia, the addition of fluoride was ultra vires the power of the local authority. She succeeded in this argument.

124. She also argued that the supply of fluoride would be for the express purpose of preventing dental caries and that consequently the respondents would be supplying a "medicinal product" for a "medicinal purpose" under the Medicines Act 1968. The argument was that the respondents needed a licence under that Act to lawfully supply fluoride.

125. This definition of "medicinal product" is very similar to the definition of medicine in the Medicines Act 1981 as it was prior to its amendment in 2014.[11]

126. Although not referred to in the judgment s 130 provide relevantly:

> 130 Meaning of "medicinal product" and related expressions.
> (1)Subject to the following provisions of this section, in this Act "medicinal product" means any **substance or article** (not being an instrument, apparatus or appliance) which is **manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways, that is to say—**
>
> **(a)use by being administered to one or more human beings or animals for a medicinal purpose;**

[11] At pp 243 to 245

> (b)use, in circumstances to which this paragraph applies, as an ingredient in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose.
>
> (2)In this Act "a medicinal purpose" means any one or more of the following purposes, that is to say—
>
> (a)**treating or preventing disease**;
>
> (b)diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;
>
> (c)contraception;
>
> (d)inducing anesthesia;
>
> (e)otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.
>
> (3)In paragraph (b) of subsection (1) of this section the reference to use in circumstances to which that paragraph applies is a reference to any one or more of the following, that is to say—
>
> (a)use in a pharmacy or in a hospital;
>
> (b)use by a practitioner;
>
> (c)use in the course of a business which consists of or includes the retail sale, or the supply in circumstances corresponding to retail sale, of herbal remedies. (emphasis added)

127. In response to Mrs McColl's arguments about fluoride being a "medicinal product" Lord Jauncey said at p 244:

> Section 130 defines "medicinal product" and I am satisfied that fluoride in whatever form it is ultimately purchased by the respondents falls within the definition. However it is the supplier of the medicinal product and not the purchaser thereof who requires to be licensed.

128. The judge also observed that he had not found it necessary to determine whether a supply of drinking water fluoridated to 1 ppm would otherwise be the supply of a medicinal product.[12]

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[12] p 245

SECOND ISSUE: LEGAL CONSEQUENCES OF HFA AND SSF BEING MEDICINES

129. If HFA and SSF are medicines under the Medicines Act, the Ministry of Health must take steps that HFA and SSF comply with the requirements of the Medicines Act. Such requirements appear to include the following.

130. First, the Minister of Health's consent is required to the distribution of HFA and SSF under ss 20 to 22. The Minister has not granted consent.

131. Section 20(2) of the Medicines Act provides that no person shall sell or distribute by way of gift or loan or sample or in any other way, any new medicine before the consent of the Minister of Health has been notified in the *Gazette*.

132. A new medicine is defined in s 3(3):

> (3) In this Act, unless the context otherwise requires,—
>
> **new medicine** means—
>
> (a) Any medicine that has not been generally available in New Zealand—
>
> (i) Before the commencement of this Act; or
>
> (ii) At any time during the period of 5 years immediately preceding the date on which it is proposed to become so available:
>
> (b) Any medicine that, immediately before the commencement of Part 2 of this Act, was a therapeutic drug to which section 12 of the Food and Drug Act 1969 applied, and in respect of the sale or distribution of which the Minister had not given his consent under that section:
>
> (c) Any medicine that becomes a medicine within the meaning of this Act for the first time after the commencement of this Act:
>
> (d) Any medicine that is referred to the Minister under section 24(5) of this Act:

133. The process for obtaining the Minister's consent is contained in ss 21 and 22 of the Medicines Act.

134. Any application must include the following information:

134.1. The name under which the medicine will be distributed;

134.2. The detail of the method of manufacture;

134.3. A full statement of the ingredients;

134.4. A description of the quality of the raw materials used;

134.5. A description of the form or forms of the medicine;

134.6. The proposed or recommended dosage and frequency of dosage and manner in which medicine is to be administered;

134.7. The purposes for which the medicine will be recommended to be used;

134.8. Reports of any test made to establish the safety of the medicine;

134.9. Reports of any tests made to control the strength, quality, purity or safety of the medicine and of the method of testing;

134.10. Any reports relation to the safety of the medicine.

135. Section 22(1) provides that on receipt of an application the Minister is to consider all the information relating to the medicine and such other matters as appear relevant, and as far as practicable, weigh the likely therapeutic value of the medicine against the risk of the use of the medicine injuriously affecting the health of any person.

136. A person who contravenes s 20(2) commits an offence and if a body corporate is liable to a fine not exceeding $100,000.

137. Secondly, the manufacturers of HFA and SSF require a licence from the Director General of Health: ss 17(1)(a) and Part 3 of the Medicines Act. No licence has been granted to any manufacturer of HFA and SSF.

138. A person who contravenes s 17 of the Medicines Act commits an offence and is liable on conviction to a fine not exceeding $40,000.

139. Thirdly, to the extent HFA and SSF are unapproved medicines they are subject to ss 25 and 29. Under ss 25 and 29 the administration of unapproved medicines is restricted to authorised prescribers and medical practitioners. Under s 29 the Director General of Health must be notified of any sale or supply or an unapproved medicine.

140. An authorised prescriber means a nurse practitioner, optometrist, practitioner, registered midwife or designated prescriber: s 2.

141. As a local authority is not an authorised prescriber or medical practitioner it is not permitted to administer HFA and SSF under the Medicines Act.

142. Further ss 25 and 29 contemplate that any administration of an unapproved medicine will be to a particular patient. Medsafe's guidelines on the use of unapproved medicines on its website also identify the application of Rights 6 (right to be fully informed) and 7 (right to give informed consent) of the Code of Health and Disability Services Consumers' Rights to the administration of unapproved medicines.

143. These rights are set out in full in Appendix B.

144. Fourthly, provisions relating to the packaging and labelling of medicines, and maintaining records will need to be complied with: ss 44 and 45 and the Regulations.

Conclusion

145. HFA and SSF are substances administered to human beings for a therapeutic purpose, ie to prevent dental decay, and have a pharmacological mechanism of action, namely mineralisation of tooth enamel.

146. They easily satisfy the criteria of a medicine under the Medicines Act.

147. The Ministry is acting inconsistently with the Act and its own rules by not regulating HFA and SSF as medicines. Any other substance containing fluoride administered for a therapeutic purpose is considered to be a medicine unless exempted under the Regulations, eg sodium fluoride tablets are a pharmacy-only medicine.

148. Further the Ministry exercises great vigilance when it comes to dietary supplements, for example, that claim to have a therapeutic purpose. The Ministry takes steps to notify suppliers that such claims are not permitted under the Medicines Act. That two substances such as HFA and SSF that have an uncontroverted therapeutic purpose and pharmacological mechanism of action have fallen under the Ministry's enforcement radar is extraordinary.

149. Given that HFA and SSF are administered to populations without informed consent (totally contrary to ethical medicine delivery principles) it is extremely important that they are subjected to Medicines Act control. That at present they are hazardous substances that contain mercury, arsenic and lead, is a further reason to ensure that they meet Medicines Act standards, including the requirements of clinical trials and testing.

150. The plaintiff seeks the following declarations:

150.1. A declaration that when sold to and supplied or distributed by local authorities for the purpose of CWF, HFA and SSF are medicines under the Medicines Act.

150.2. A declaration that the Ministry of Health is required to take all necessary steps to ensure that the manufacture, distribution, sale and supply of HFA and SSF complies

with the Medicines Act and Regulations.

Dated: 18th September 2014

Lisa Hansen

Lisa Hansen

Counsel for the plaintiff

APPENDIX A

22 October 2003 to 30 June 2014

3 Meaning of "medicine", "new medicine", "prescription medicine", and "restricted medicine"

(1) Subject to subsection (2) of this section, in this Act, unless the context otherwise requires, the term **medicine** means any substance or article, other than a medical device, that is manufactured, imported, sold, or supplied wholly or principally—

(a) For administering to one or more human beings for a therapeutic purpose; or

(b) For use as an ingredient in the preparation of any substance or article that is to be administered to one or more human beings for a therapeutic purpose, where it is so used—

(i) In a pharmacy or a hospital; or

[(ii) By a practitioner, or registered midwife, or designated prescriber, or in accordance with a standing order; or]

(iii) In the course of any business that consists of or includes the retail sale, or the supply in circumstances corresponding to retail sale, of herbal remedies; or

(c) For use as a pregnancy test.

(2) In this Act, unless the context otherwise requires, the term "medicine" does not include—

(a) Substances used in dental surgery for filling dental cavities; or

(b) Bandages and other surgical dressings, except medicated dressings where the medication has a curative function that is not limited to sterilising the dressing; or

(c) Any radioactive material within the meaning of section 2(1) of the Radiation Protection Act 1965; or

(d) Any animal food in which a medicine is incorporated; or

(e) Any animal remedy; or

(f) Any other substance or article of a kind or belonging to a class that is declared by regulations made under this Act to be a kind or class of substance or article that is not a medicine for the purposes of this Act.

1 August 1984 to 30 June 2014

4 Meaning of "therapeutic purpose"

In this Act, unless the context otherwise requires, the term **therapeutic purpose** means—

(a) Treating or preventing disease; or

(b) Diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition; or

(c) Effecting contraception; or

(d) Inducing anaesthesia; or

(e) Altering the shape, structure, size, or weight of the human body; or

(f) Otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way; or

(g) Cleaning, soaking, or lubricating contact lenses.

APPENDIX B: RIGHTS 6 AND 7 CODE OF HEALTH AND DISABILITY SERVICES CONSUMERS' RIGHTS

RIGHT 6

Right to be Fully Informed

1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including -

a) An explanation of his or her condition; and

b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and

c) Advice of the estimated time within which the services will be provided; and

d) Notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval; and

e) Any other information required by legal, professional, ethical, and other relevant standards; and

f) The results of tests; and

g) The results of procedures.

2) Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.

3) Every consumer has the right to honest and accurate answers to questions relating to services, including questions about -

a) The identity and qualifications of the provider; and

b) The recommendation of the provider; and

c) How to obtain an opinion from another provider; and

d) The results of research.

4) Every consumer has the right to receive, on request, a written summary of information provided.

RIGHT 7

Right to Make an Informed Choice and Give Informed Consent

1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.

2) Every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the consumer is not competent.

3) Where a consumer has diminished competence, that consumer retains the right to make informed choices and give informed consent, to the extent appropriate to his or her level of competence.

4) Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where -

a) It is in the best interests of the consumer; and

b) Reasonable steps have been taken to ascertain the views of the consumer; and

c) Either, -

i. If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of

the services is consistent with the informed choice the consumer would make if he or she were competent; or

ii. If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.

5) Every consumer may use an advance directive in accordance with the common law.

6) Where informed consent to a health care procedure is required, it must be in writing if -

a) The consumer is to participate in any research; or

b) The procedure is experimental; or

c) The consumer will be under general anaesthetic; or

d) There is a significant risk of adverse effects on the consumer.

7) Every consumer has the right to refuse services and to withdraw consent to services.

8) Every consumer has the right to express a preference as to who will provide services and have that preference met where practicable.

9) Every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure.

10) No body part or bodily substance removed or obtained in the course of a health care procedure may be stored, preserved, or used otherwise than

(a) with the informed consent of the consumer; or

(b) For the purposes of research that has received the approval of an ethics committee; or

(c) For the purposes of 1 or more of the following activities, being activities that are each undertaken to assure or improve the quality of services:

(i) a professionally recognised quality assurance programme:

(ii) an external audit of services:

(iii) an external evaluation of services.

MEDSAFE
NEW ZEALAND MEDICINES
AND MEDICAL DEVICES
SAFETY AUTHORITY
A BUSINESS UNIT OF
THE MINISTRY OF HEALTH
www.medsafe.govt.nz

22 February 2008

The General Manager
[redacted]
PO Box [redacted]
[redacted]
[redacted]
Auckland 0757

Dear Sir / Madam

Compliance with the Medicines Act 1981

I am writing to:

- advise that a recent compliance review of information about products advertised on your web site has found material that is not compliant with the requirements of the Medicines Act 1981; and
- to ask you to take corrective action by 4 April 2008.

The concerns have arisen because statements you make for some of these products are claims that indicate or imply a therapeutic purpose for the product. Apart from a few limited circumstances, such claims are not permitted unless the product has been approved as a medicine. The approval process involves an application (accompanied by an appropriate fee) and an evaluation of the safety and efficacy of the product, after which, the Minister of Health may grant consent for you to advertise, sell and/or distribute the product as a medicine.

As you are a practitioner of natural medicine you may formulate a herbal remedy for a patient following a consultation. You may also manufacture, sell or supply herbal remedies providing that you do not make any therapeutic claims for that product. The exemptions for practitioners and herbal remedies are specified in part 2 of the Medicines Act.

The enclosed advertising guideline provides information to assist you take corrective action. It is very important that your product labels, any advertising material or supporting literature for your products (including websites) do not contain any therapeutic claims or references to therapeutic purposes.

Please make sure you are familiar with the requirements of relevant legislation such as the Dietary Supplements Regulations 1985 and the Medicines Act 1981 to ensure that your products are compliant. This legislation is available on-line at www.legislation.govt.nz or may be purchased from Bennetts Bookshops.

Products that are presented as medicines are regulated by the Medicines Act 1981 and heavy penalties can be imposed on companies who distribute, market or advertise a medicine without consent from the Minister of Health.

Please confirm that you will modify the claims made for your products by 4 April 2008 and advise when you have completed the corrective action. Medsafe's compliance monitoring programme is ongoing and you are advised that further action may be taken if you continue to advertise and/or distribute an unapproved medicine.

Please contact me on 0800 266 380 if you wish to discuss this matter or require further information or assistance.

Yours sincerely,

Carole Firth
Advisor

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AND MEDICAL DEVICES
SAFETY AUTHORITY
A BUSINESS UNIT OF
THE MINISTRY OF HEALTH
www.medsafe.govt.nz

11 March 2008

The General Manager
[redacted]
Auckland

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- to ask you to take corrective action by 22 April 2008.

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Please confirm that you will modify the claims made for your products by 22 April 2008 and advise when you have completed the corrective action. Medsafe's

compliance monitoring programme is ongoing and you are advised that further action may be taken if you continue to advertise and/or distribute an unapproved medicine.

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Yours sincerely,

Carole Firth
Advisor

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THE MINISTRY OF HEALTH
www.medsafe.govt.nz

11 March 2008

The General Manager
[redacted]
Auckland 0630

Dear Sir / Madam

Compliance with the Medicines Act 1981

Your website has been reviewed as part of a compliance review. You are advertising and distributing the following products on the website [redacted] in breach of the Medicines Act 1981:

- Omega 3 Capsules
- Shark Cartilage Capsules
- Squalene Capsules
- Shark Liver Oil Capsules
- Green-Lipped Mussel Capsules
- Royal Jelly Extract Capsules
- Bee Propolis Tincture Triple Strength
- Deer Placenta Capsules
- Deer Velvet Capsules
- Deer Blood Capsules
- Deer Pizzle Capsules
- Super Sheep Placenta Capsules
- Liquid Calcium with Vitamin D Capsules
- Garlic Oil Capsules
- Complete Vitamin C Complex Tablets
- Colostrum 200 Tablets
- Spirulina Tablets
- Grape Seed Extract Capsules
- Evening Primrose Oil Capsules
- LiverMax Milk Thistle Caps
- Shark Cartilage Capsules
- Joint Complex Capsules

On your website these products are accompanied by statements that imply a therapeutic purpose. Information on disease conditions also refers to a number of the above products as recommended treatments.

The Medicines Act (1981) (sections 3 and 4) defines a product for which a therapeutic purpose is claimed as a medicine. The Minister of Health must give consent prior to the advertising or distribution of such products. No such consent has been given in respect of any of the above listed products.

The distribution of a medicine prior to the Minister of Health giving consent to such distribution is contrary to section 20 of the Medicines Act 1981 and is an offence for which the maximum penalty on conviction for a body corporate is $100, 000.

Please note that products that are intended to be used as dietary supplements must comply with the Dietary Supplements Regulations 1985. Therapeutic claims cannot be made regarding dietary supplements.

Please find enclosed a copy of our Therapeutic Claims Guidance for complying with the Medicines Act which may assist you in understanding the requirements.

Please immediately modify your website to remove all therapeutic claims.

We have also noted that your product range includes the following food-type products:

- Colostrum Powder
- Barley Powder
- Manuka Honey

We have advised the Director (Compliance and Investigation) of New Zealand Food Safety Authority (NZFSA), who regulates these products, that the advertising for these implies they have a therapeutic purpose. NZFSA may also contact you.

Please respond to this letter in writing by 4 April 2008 confirming that you have modified your website. Upon receipt of your written response, Medsafe will consider whether further action may be required.

If you would like further information or wish to discuss the above matter, please phone 0800 266380.

Yours sincerely

Donna Jennings
Advisor (Science)
Tel 04 819 6873
Fax 04 819 6807
Email donna_jennings@moh.govt.nz

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NEW ZEALAND MEDICINES
AND MEDICAL DEVICES
SAFETY AUTHORITY
A BUSINESS UNIT OF
THE MINISTRY OF HEALTH
www.medsafe.govt.nz

14 March 2008

[redacted]

[redacted]

Compliance with the Medicines Act 1981

Your website [redacted] and your advertisement in the December 2007 edition of the [redacted] have been appraised as part of a compliance review. You are advertising and distributing the following products via these media in breach of the Medicines Act 1981:

- [redacted]
- Selenium
- [redacted] Capsules
- [redacted] Silica
- [redacted] SAMe
- [redacted] Gel
- [redacted]
- [redacted]
- [redacted]
- [redacted] Scar Treatment
- [redacted] Cleanse System
- Silver Solution at 14 ppm
- [redacted]
- [redacted] Weight Management
- [redacted] Haemorrhoid Treatment
- Guarana Capsules
- Glucosamine Chondroitin & MSN Capsules
- [redacted] Phosphatidyl Ginkgo Boost

On your website and/or advertisement these products are accompanied by statements that imply a therapeutic purpose.

The Medicines Act (1981) (sections 3 and 4) defines a product for which a therapeutic purpose is claimed as a medicine. The Minister of Health must give consent prior to the advertising or distribution of such products. No such consent has been given in respect of any of the above listed products.

The distribution of a medicine prior to the Minister of Health giving consent to such distribution is contrary to section 20 of the Medicines Act 1981 and is an offence for which the maximum penalty on conviction for a body corporate is $100, 000.

Please note that products that are intended to be used as dietary supplements must comply with the Dietary Supplements Regulations 1985. Therapeutic claims cannot be made regarding dietary supplements.

Please find enclosed a copy of our Therapeutic Claims Guidance for complying with the Medicines Act which may assist you in understanding the requirements.

Please immediately modify your website to remove all therapeutic claims.

We have also noted that the folic acid on your website exceeds the maximum daily dose permitted by the Dietary Supplement Regulations 1985.

Please respond to this letter in writing by 11 April 2008 confirming that you have modified your website. Please review all your advertising, including labelling, for compliance with the Medicines Act 1981. Upon receipt of your written response, Medsafe will consider whether further action may be required.

If you would like further information or wish to discuss the above matter, please phone 0800 266380.

Yours sincerely

Donna Jennings
Advisor (Science)
Tel 04 819 6873
Fax 04 819 6807
Email donna_jennings@moh.govt.nz

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NEW ZEALAND MEDICINES
AND MEDICAL DEVICES
SAFETY AUTHORITY
A BUSINESS UNIT OF
THE MINISTRY OF HEALTH
www.medsafe.govt.nz

28 January 2008

General Manager
[redacted]
P O Box [redacted]
[redacted]

Dear Sir or Madam

[redacted]

Your website [redacted] has been reviewed as part of a compliance review. You are advertising and distributing [redacted] on your website [redacted] in breach of the Medicines Act 1981.

These products are advertised as containing N-acetyl L-cysteine, also known as acetylcysteine. Acetylcysteine is classified as a pharmacy-only medicine if the daily dose does exceeds 1g /day. Its presence indicates that you intend a therapeutic purpose for the product. The Medicines Act (1981) (sections 3 and 4) defines a product for which a therapeutic purpose is claimed as a medicine.

Consent of the Minister of Health is required prior to any advertising or distribution of a medicine. The distribution of a medicine prior to the Minister of Health giving consent to such distribution is contrary to section 20 of the Medicines Act 1981 and is an offence for which the maximum penalty on conviction for a body corporate is $100, 000.

Please immediately remove all products containing this ingredient from sale and remove or withdraw all advertising. Please respond to this letter in writing by 7 February 2008 confirming that you have done this. Please indicate in your response the quantity of stock you have in your possession and provide sales information for the past 12 months. Upon receipt of your written response, Medsafe will consider whether further action may be required.

Please contact me on 0800 266 380 if you wish to discuss this matter or require further information or assistance.

Yours sincerely

Derek Fitzgerald

Donna Jennings
Advisor (Science)
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Fax 04 819 6807
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29 February 2008

The General Manager
[redacted]
Auckland 0630

Dear Sir / Madam

We recently reviewed information about products on your website for compliance with the requirements of the Medicines Act 1981. During this review we have noted that some ingredients in your products are present at quantities that exceed the daily maximum dose permitted by the Dietary Supplements Regulations 1985.

The following products contain folic acid, vitamin A and/or vitamin B_{12} at levels non-compliant with the Dietary Supplements Regulations:

- [redacted]
- [redacted]
- [redacted]

The Dietary Supplements Regulations specify the maximum daily doses for these ingredients as:

- Folic acid 300 µg
- Vitamin A 3 mg (equivalent to 10 000 IU)
- Vitamin B_{12} 50 µg

This legislation is available on-line at www.legislation.govt.nz or may be purchased from Bennetts Bookshops.

The Dietary Supplements Regulations are administered by the New Zealand Food Safety Authority (NZFSA). Please call the Director (Compliance and Investigation) on 0800 693 721 if you wish to discuss the regulations.

Yours sincerely

C Firth

Carole Firth
Advisor