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	**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

DEFENDANT'S SUBMISSIONS

26 September 2014

Judicial Officer: MacKenzie J
Next Event Date: Hearing 2 October 2014

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Introduction

1. The plaintiff is opposed to community water fluoridation. This case is the plaintiff's second challenge to the lawfulness of community water fluoridation. In *New Health Inc v South Taranaki District Council* [1] this Court dismissed the plaintiff's challenge to the South Taranaki District Council decision to fluoridate its community's water supply, finding: it was lawful under the Local Government Act 2002 and the Health Act 1956; it did not breach s 11 of the New Zealand Bill of Rights Act 1990 (as whilst fluoridation has a therapeutic purpose, the means by which that purpose is effected does not constitute medical treatment); and that fluoridated water did not come within the definition of food for the purposes of the Medicines Act 1981 (Medicines Act).

2. Because this Court found fluoridation has a therapeutic purpose, the plaintiff now seeks declarations that the chemicals used by local authorities to treat community water supplies for the purpose of fluoridation, hydrofluosilicic acid (HFA) and sodium silicofluoride (SSF), are medicines as defined in the Medicines Act. The plaintiff, however, does not claim that the fluoridated water itself is a medicine. The plaintiff does not allege any risks to the public arise from the failure of these chemicals not being regulated under the Medicines Act, but considers that requiring these chemicals to comply with that Act would provide a regulatory obstacle to the Ministry of Health's promotion of water fluoridation.

3. The defendant says it has never had cause to consider the chemicals used in water fluoridation could potentially be a medicine for the purposes of the Act. The defendant says the Act cannot be interpreted such that these chemicals are a medicine, including because such an interpretation would be impractical and unnecessary. It would also be illogical given the plaintiff's acceptance that fluoridated water itself is not a medicine.[2]

Issues for determination

4. The relevant facts regarding the use of the chemicals HFA and SSF in water treatment processes are not in dispute. Whilst the plaintiff disagrees with the Ministry recommending water fluoridation as a safe, effective and affordable way to prevent tooth decay, the Court is not being asked to consider the merits

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1 *New Health New Zealand Inc v South Taranaki District Council* [2014] NZHC 395, [2014] 2 NZLR 834.
2 Plaintiff's submissions at [82]

of fluoridation and the wealth of scientific research relating to the merits. The only questions before the Court are those of statutory interpretation outlined below. The plaintiff does not claim fluoridated water is a medicine.[3]

5. The issue for determination is the whether the chemicals HFA and SSF, when used for community water fluoridation, come within the definition of a "medicine" in s 3(1)(a) of the Medicines Act. In particular, the issue is whether:

5.1 The use of the chemicals in community water fluoridation comes within the definition of "administer" in s 2 of the Medicines Act.

6. When considering this issue, the defendant says it is necessary to consider whether in any event, the context in which HFA and SSF are used means they are outside of the purpose of the Medicines Act. The question is whether in the circumstances of this case, the "context otherwise requires" (in accordance with s 5(1) of the Interpretation Act 1999) such that these chemicals cannot be interpreted as falling within the definition of medicine.

Summary

7. In summary, the defendant says this application for declaratory relief should be dismissed. The defendant submits the chemicals HFA and SSF that are used for community water fluoridation do not fall within the definition of "medicine" in s 3(1)(a) of the Act as the plaintiff alleges because:

7.1 The definition requires that the chemicals must be a substance that is "manufactured, imported, sold or supplied wholly or principally for *administering* to 1 or more human beings for a therapeutic purpose" and the addition of the chemicals to community water supplies cannot be said to be "administering" the chemicals, given the definition of "administer" in s 2 of the Act. Fluoridated water (and the chemicals used in treating that water) is supplied by local authorities for the purposes of human consumption and use: it is not administered. It is illogical for HFA and SSF to be a medicine under the Act in its undiluted form but not in its diluted form.

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3 Plaintiff's submissions at [82]. It is noted that in *New Health New Zealand Inc v South Taranaki District Council* [2014] NZHC 395, [2014] 2 NZLR 834 at [44]-[45] the Court dismissed the plaintiff's claim that fluoridated water could

7.2 Further, if the Court finds there is ambiguity as to whether the chemicals used in water fluoridation can be interpreted as falling within the definition of "medicine" in s 3(1)(a), the context is such that the definition should not apply. In the circumstances of this case, the "context otherwise requires". The purpose of the Act is the protection of public safety from the use of medicines and other medical products, through providing for their safety, quality and efficacy. As a matter of common sense the regulation of community water fluoridation does not properly fit within that purpose and is regulated by other controls including under the Local Government Act 2002 and the Health Act 1956 by the issuing of the drinking water standards. Those controls sufficiently protect the public from any health risks and no useful purpose or public interest would be served by HFA and SSF coming within the definition of medicine in the Act. Water fluoridation has been safely undertaken for over sixty years and proven to be effective. It would be an absurd result to now require manufacturers to be licensed under the Medicines Act and be subject to other relevant requirements such as labelling or advertising requirements.

Pleadings and plaintiff's evidence

8. This plaintiff seeks declaratory relief under the Declaratory Judgments Act 1908 (DJA) and the Judicature Amendment Act 1972 (JAA) in the following terms: "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".[4]

9. For completeness the defendant notes it accepts no jurisdictional issues arise here as the proceeding involves narrow issues of statutory interpretation amenable to consideration under the DJA.

10. The defendant's evidence consists of two affidavits:

10.1 The affidavit of Stewart Jessamine, Group Manager of the Medsafe (New Zealand Medicines and Medical Devices Safety Authority)

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not be supplied without the consent of the Minister of Health under the Medicines Act as water is not a food, applying *Diet Tea Co Ltd v Attorney-General* [1986] 2 NZLR 693 (HC).

which is responsible for administering most aspects of the Act and the Chair of the New Zealand Medicines Classification Committee. Dr Jessamine's expertise includes providing specialist advice on clinical issues relating to the safety, and efficacy of medicines.[5] His evidence is that the defendant has never to his knowledge had cause to consider that fluoridated water, or the chemicals used in water fluoridation could potentially be medicines under the Act.[6] His evidence states that a pragmatic filter must be applied to the legislation when examining the context in which the chemical or product is supplied, its dose form, its concentration and its intended use before determining whether the product is a medicine.[7]

10.2 The affidavit of Paul Francis Prendergast, a civil engineer, previously the Principal Public Health Engineer at the Ministry of Health who is a specialist in water management and a long standing member of the committee that develops the New Zealand drinking water standards: He discusses the drinking water standards, the monitoring of water supplies to ensure their safety; the chemical fluoride and fluoride compounds; the water fluoridation process and how the standards and testing apply to fluoridated water. The purpose of his evidence is to satisfy the Court that the use of chemicals in water fluoridation is subject to sufficient controls to ensure it is safe and effective.

Factual background – water fluoridation

11. Water fluoridation (the process of increasing fluoride levels in our water supply), is a practice recommended by the Ministry of Health as a safe, effective and affordable way to prevent tooth decay.[8] The plaintiff is opposed to water fluoridation for various reasons and disagree that it is safe and effective.[9]

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4 Plaintiff's submissions at [28].
5 Affidavit of Stewart Sinclair Jessamine at [4].
6 Affidavit of Stewart Sinclair Jessamine at [26]-[27].
7 Affidavit of Stewart Sinclair Jessamine at [25].
8 Affidavit of Stewart Sinclair Jessamine at [13]-[15] noting this view is shared by other public health authorities and medical science bodies and international organisations and is underpinned by sixty years of scientific research (including those set out in exhibit A and the Water Fluoridation Review undertaken by Royal Society of New Zealand and Office of the Prime Minister's Chief Science Advisor http://www.pmcsa.org.nz/wp-content/uploads/Health-effects-of-water-fluoridation-Aug2014.pdf).
9 Affidavit of Patrick David Sloan dated 1 April 2014 at [10] and Second Affidavit of Patrick David Sloan dated 23 June 2014 at [3]-[47].

12. Water fluoridation was first introduced into New Zealand in 1954 as the naturally occurring levels of fluoride in our water are relatively low.[10]

13. Under the Local Government Act 2002 local authorities are obliged to provide drinking water supplies to the community and maintain water services. Under that Act there is an implied power to fluoridate and the decision to fluoridate is one for each local authority to make.[11]

14. The *Drinking-water Standards for New Zealand* (DWSNZ) issued by the Minister of Health under s 69O of the Health Act 1956 are the primary tool for ensuring the safety of drinking water as public drinking water suppliers are required to take all practicable steps to comply with the standards.[12]

15. The DWSNZ are discussed in detail in the affidavit of Paul Prendergast.[13] In brief, the standards are based on World Health Organization Guidelines. The standards set maximum allowable values (MAV) to any determinand (substance or organism in water that may be estimated or determined reasonably accurately).[14] The MAVs apply to any determinand that may be found in the water after treatment whether from: the source water (e.g. microorganisms, pesticides, industrial waste); the treatment process (e.g. fluoride and impurities in water treatment chemicals); the distribution system (e.g. bacteria and disinfection by-products); or the plumbing (e.g. copper and lead).

16. MAVs are mostly very conservative, incorporating a safety factor from 100 to 3000 depending on the level of uncertainty. The MAV for fluoride is 1.5mg/L. This rate has remained unchanged for 30 years.[15]

17. The DSWNZ require public water suppliers to test water regularly to show compliance, report any exceedances and take corrective action. Whilst the DSWNZ requires weekly sampling of fluoride levels, most water treatment plants have online monitoring that continuously checks levels and activates an

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10 *New Health New Zealand Inc v South Taranaki District Council* [2014] NZHC 395, [2014] 2 NZLR 834 at [1].

11 *New Health New Zealand Inc v South Taranaki District Council* [2014] NZHC 395, [2014] 2 NZLR 834 at [22]-[25]; [117].

12 Part 2A of that Act contains detailed provisions directed to the promoting the supply of safe and wholesome drinking water, s 69A(1). These provisions as they relate to water fluoridation are helpfully discussed in *New Health* at [27]-[36].

13 At [12]-[27] and [46]-[48] and he attaches a current version of the *Drinking-water Standards for New Zealand* as exhibit "A".

14 Affidavit of Paul Francis Prendergast, Exhibit "A", *Drinking-water Standards for New Zealand*, p 148.

alarm if the MAV is exceeded.[16] Ministry of Health records show that over the last seven years, a total of 21,279 fluoride samples were analysed and only 13 exceeded the MAV of 1.5mg/L (the highest recorded value being 2.12mg/L). This contrasts with other jurisdictions, for example the United States, where the standards allow fluoride of 4mg/L.[17]

18. In addition to the DWSNZ the industry standard recently published, the Water New Zealand Guideline *Supply of Fluoride for Use in Water Treatment: May 2014* (Water NZ Guideline) comprehensively cover the monitoring and testing applied to fluoridated water to regulate the addition of fluoride compounds to water supplied to the consumer.[18] The Water NZ Guideline sets the allowable levels of impurities (e.g. arsenic, lead) in the supplied fluoride.[19]

19. The packaging, transporting, labelling, handling and storage of fluoride compounds are subject to a range of regulations and rules including under the Hazardous Substances and New Organisms Act 1996 (HAZNO) and Regulations, and Land Transport Rules.[20]

20. As well as knowing the maximum level the impurities can contribute to the treated drinking water as per the Water NZ Guideline the DWSNZ sets MAVs for any such impurities from all sources and the monitoring programme ensures these will not be exceeded.

21. When producing drinking water a number of different chemicals may be added during the water treatment process for different purposes, for example chlorine is added for disinfection.[21]

22. Fluoridation is not a treatment process and is generally undertaken after the processes of clarification and chlorination. HFA and SSF are the chemical compounds that are mainly used for water fluoridation. The fluoride

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15 Affidavit of Paul Francis Prendergast at [46].
16 Affidavit of Paul Francis Prendergast at [41].
17 Affidavit of Paul Francis Prendergast at [48].
18 This version replaced the 1997 version and is attached as exhibit "B" to the affidavit of Paul Francis Prendergast.
19 Ibid. HFA and SSF will inevitably contain small amounts of impurities, including heavy metals. The Water New Zealand Guideline uses the term "specific impurity limits" (SIL) to cover all metallic determinands that have MAVs in the DWSNZ.
20 See Water New Zealand Guideline *Supply of Fluoride for Use in Water Treatment: May 2014* pp5-7 , exhibit "B" in the affidavit of Paul Francis Prendergast.
21 Discussed in affidavit of Paul Francis Prendergast at [28]-[39].

chemicals are added as a metered dose for a given rate of water flow via a feed system.[22]

23. Typically HFA is used by the larger water suppliers as it is a more cost effective option. HFA is manufactured in New Zealand as a co-product of the superphosphate industry, as the phosphate rock used to make the fertiliser contains fluoride (which comes from the bones and teeth of ancient fish that are components in the rock).[23] The compounds dissolve fully in water to release fluoride ions that are identical to those found naturally in water (a fluoride ion is the same, regardless of where it came from).[24]

24. In summary, whilst HFA or SSF may contain trace metals or other impurities the regular testing/monitoring ensures any additional impurities in the drinking water added by the use of these chemicals are below the maximum safe limits set out in the DWSNZ.[25]

Medicines Act 1981

Overview and purpose

25. The Medicines Act is part of a wider statutory framework that provides for the importation, exportation, distribution and use of chemical substances to control chemical substances that pose risks of harm, either broadly or in specific situations. This framework includes HAZNO, the Health Act 1956, and the Misuse of Drugs Act 1975. Other Acts in addition to the Medicines Act that impose specific controls over substances or products manufactured for use by professionals and in the wider community in specific situations, include the Food Act 1981 (and Dietary Supplements Regulations 1984), Agricultural Compounds and Veterinary Medicines Act 1997, Smoke-Free Environments Act 1990, Sale and Supply of Alcohol 2012 and Psychoactive Substances Act 2013.[26]

26. The Medicines Act regulates medicines, related products, and medical devices in New Zealand.[27] It imposes extensive controls on the manufacture,

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22 Affidavit of Paul Francis Prendergast at [31]-[33].

23 Affidavit of Paul Francis Prendergast at [44]-[45].

24 Affidavit of Paul Francis Prendergast at [43]. HFA and SSF are hazardous substances under the Hazardous Substances and New Organisms Act 1996 (HAZNO). See Affidavit of Paul Francis Prendergast at [44].

25 Affidavit of Paul Francis Prendergast at [50]-[54].

26 Refer discussion in affidavit of Stewart Sinclair Jessamine at [8]-[12].

27 "Related product" is defined as "any cosmetic or dentifrice or food in respect of which a claim is made that the substance or article is effective for a therapeutic purpose; but does not include— (a) any medicine: (aa) any

importation, packaging and distribution of medicines. The Ministry of Health is responsible for administering the Act and its accompanying regulations, the Medicines Regulations 1984 (Medicines Regulations).

27. The purpose of the Medicines Act is to ensure that the products described above are safe and effective for use by consumers.[28] As summarised at the time of the Act's inception by the responsible Minister, Hon G F Fair: "The fundamental aim of all medicines policies is to ensure that medicines of adequate quality are available to serve the health needs of the population, and that they are properly used."[29]

28. The case of *Ministry of Health v Pacific Pharmaceuticals Limited*[30] concerned an appeal by the Crown against sentences imposed for breaches of the Act for sale and distribution of capsules of an extract from green lipped mussels which media publicity suggested might "cure" cancer.[31] The Court found the District Court correctly referred to the Act as:

> "...Public welfare legislation designed to protect the public from potential health risks in relation to claims to therapeutic benefits of products that have not had the appropriate clinical trials and testing."

29. When discussing relevant considerations for penalty the Court noted the purpose of the Act is consumer protection, that the global industries of medicine and dietary supplements are immense and have potential for vast profits by exploitation of consumers.[32]

30. As Dr Jessamine states the three elements of safety, quality and efficacy of medicines must all be assured if the public is to be adequately protected from products which have the potential to harm if they do not meet standards claimed for them, if they are used inappropriately.[33]

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medical device: (b) any 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 related product for the purposes of this Act."

28 The Act contains no express statement of its purpose, however this can be reasonably inferred from the nature and provisions of the Act.

29 (26 August 1981) 2984 NZPD 2988.

30 *Ministry of Health v Pacific Pharmaceuticals Limited* HC Auckland A165/100, 16 February 2001.

31 There was no issue in that case that the capsules would come within the definition of a new medicine for the purposes of s 20 of the Act.

32 *Ministry of Health v Pacific Pharmaceuticals Limited* HC Auckland A165/100, 16 February 2001 at [22].

33 Affidavit of Stewart Sinclair Jessamine at [17].

Classification of medicines

31. The Act in s 3 defines "medicine", "new medicine", "pharmacy-only medicine", "prescription medicine" and "restricted medicine".

32. The classification of a medicine under one of the three types (pharmacy-only, prescription or restricted or general sale medicine) determines the extent to which its sale, supply or use is restricted under the Act. Unless an exemption applies, it is an offence under the Act for a person to sell, supply or distribute a classified medicine.[34]

33. The Medicines Regulations sit alongside the Act and contain a list of classified medicines in Schedule 1. Prescription medicines are listed in Part 1 of the Schedule; restricted medicines in Part 2; and pharmacy-only medicines in Part 3.

34. Medicines that are not classified as one of these three types are treated as general sale medicines (medicines simpliciter).[35] The Act imposes fewer restrictions on the retail sale or supply of these medicines.

35. The Act provides for appointment by the Minister of advisory or technical committees to advise him for any of the purposes of the Act (s 8) and establishes a ministerial advisory committee, the Medicines Classification Committee, to assess the degree of risk any approved medicine may pose and recommend whether restrictions should be applied to the retail sale, supply and administration of the medicine (s 9). The Committee makes recommendations to the Minister of Health, who in turn recommends classifications for each medicine. These are normally assigned by regulation made by Order in Council.[36]

Licensing scheme

36. The Act provides for a licensing scheme that applies to all parts of the medicines distribution chain, including manufacturers, wholesalers, packers, pharmacies and retailers. Section 17 provides that these persons are required to obtain a license in order to manufacture, pack and label, and sell

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[34] Medicines Act 1981, ss 18 and 78. The most serious offence is committed where the breach involves a prescription medicine: see s 18(5).

[35] Section 99 of the Medicines Act 1981 defines general sale medicines to mean medicines that may be lawfully sold in New Zealand, other than prescription medicines, restricted medicines, and pharmacy-only medicines. Under that section the Director-General of Health is required to publish a list of such medicines.

medicines.[37] Section 34, however, provides an exemption for wholesale sales of medicines simpliciter.

37. Part 3 of the Act sets out provisions relating to licenses. These include the requirements that must be satisfied in an application for a license;[38] matters relating to the grant of licenses;[39] the effect of licenses, and the activities they authorise certain persons to do in relation to medicines;[40] the duration of licenses;[41] and the requirements for display.[42]

Ministerial approval required for new medicine

38. The Act requires new medicines (as defined in s 3(3)) to be approved under s 20 before they can be sold, distributed, or advertised as a medicine in New Zealand.[43] In *Ministry of Health v Pacific Pharmaceuticals Limited*[44] the Court noted that the underlying policy of s 20 is to ensure medicines and therapeu

39. tic drugs cannot be released in New Zealand until the Ministry of Health is satisfied there are no unacceptable risks. This ensures the public is protected from any risks inherent in untested or experimental drugs.

Quality standards and other specific regulatory requirements

40. The Act sets out a range of provisions to control the quality and standards of medicines. The Act imposes a duty on importers or manufacturers to report to the Director-General any substantial untoward effects that have arisen from use of the medicine in New Zealand or elsewhere.[45] The Act also imposes a duty on importers and manufacturers to have in their possession and produce on demand, specifications of medicines.[46] The Minister has the power to prohibit the importation, manufacture, packing, sale, possession and supply of medicines.[47]

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36 Dr Jessamine is currently the chair of this Committee – refer to his affidavit at [3].

37 Section 34 provides for an exemption for wholesalers of medicines that are not prescription medicines, restricted medicines, or pharmacy-only medicines.

38 Section 50.

39 Section 51.

40 Section 52.

41 Section 53.

42 Section 54.

43 Section 20(1) states that this is subject to a number of exceptions that apply to particular practitioners in certain circumstances. These include health practitioners (s 25); pharmacists (s 26); or where medicines are being used for a clinical drug trial (s 30).

44 *Ministry of Health v Pacific Pharmaceuticals Limited* HC Auckland A165/100, 16 February 2001.

45 Section 41.

46 Section 42.

47 Section 37.

41. The Act and Regulations sets out specific requirements for the packaging and storage of medicines. These requirements are directed at ensuring medicines are kept free from contamination. A medicine must be packed and stored in a container that is impervious to the medicine,[48] and can be readily resealed after a portion of its contents have been used[49] where the quantity and nature are such that the contents is unlikely to be used on a single occasion. Medicines must be kept free from moisture, foul odours or dust[50] and creatures likely to contaminate them.[51] Storage of medicines is to be separate from any food or drink that may be contaminated by escape of the medicine.[52]

42. The Regulations set out requirements and particulars that must be specified on a label of every container of medicine. These requirements include, among other things: the appropriate designation of the medicine; the name of each active ingredient; the appropriate quantitative particulars of each active ingredient; and the name and address of the manufacturer.[53] Every container must contain any warning statement that may be required by Ministry of Health guidelines.[54]

43. The Act imposes a range of restrictions on advertisements promoting the sale of medicines or medical devices. These include prohibiting advertisements that make any statement contrary to any statement required by Regulations;[55] or omit from the medicine description any key words required by Regulations;[56] or statements regarding the nature, quality, of the medicines that are false or likely to mislead any person.[57]

Medicines Regulations - listed Fluoride medicines

44. The Medicines Regulations Schedule 1 contains three parts that list prescription, restricted and pharmacy-only medicines. Fluoride is listed as a medicine in the Schedule but only when the concentration of fluoride is significantly higher than that present in fluoridated water (that is 0.7 to 1.5 parts per million (ppm) as per the drinking water standards):

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48 Section 44(1)(a)(i).
49 Section 44(1)(a)(ii).
50 Regulation 32(1)(a)
51 Regulation 32(1) (b).
52 Regulation 36.
53 Regulation 13.
54 Regulation 22.
55 Section 57(1)(a).
56 Section 57(1)(c).
57 Section 57(1)(g).

44.1 Schedule 1 provides that "unless specific reference is made otherwise, every reference to a medicine in this schedule applies … only if the concentration of the medicine is greater than 10 milligrams per litre or per kilogram". This means that unless specific reference is made otherwise, a product is a medicine under Schedule 1 if the concentration of the substance in the product is greater than 10 milligrams per litre or per kilogram.

44.2 Regulation 58A(1)(a) provides that fluoride is not considered to be a medicine, or a related product, when it is included in toothpastes or dentrifices for the prevention of dental caries at concentrations of 15 milligrams or less per litre or per kilogram of fluoride. That is, even at a concentration 10 times higher than that found in treated drinking water, the fluoride in toothpastes or dentrifices does not amount to a medicine.

Substantive submissions

HFA and SSF not medicines

45. The defendant says the chemicals HFA and SSF when used for community water fluoridation do not come within the definition of a "medicine" in s 3 (1)(a) of the Act as:

45.1 The definition requires that the chemicals must be a substance that is "manufactured, imported, sold or supplied wholly or principally for *administering* to 1 or more human beings for a therapeutic purpose" and the addition of the chemicals to community water supplies cannot be said to be "administering" the chemicals given the definition of "administer" in s 2 of the Act; and

45.2 In any event, the context in which HFA and SSF are used means they are outside of the purpose of the Act. On this basis "context otherwise requires" and s 5(1) of the Interpretation Act 1999 applies meaning that these chemicals do not fall within the definition of a medicine.

HFA and SSF are not being "administered" to persons

46. The relevant definition of "medicine" at issue here is that contained in s 3(1)(a) which provides:

> **3 Meaning of medicine, new medicine, prescription medicine, and restricted medicine**
>
> (1) Subject to subsection (2), 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 1 or more human beings for a therapeutic purpose; or

47. To fall within the definition of medicine, the chemicals used in water fluoridation must be:

47.1 a substance or article;[58]

47.2 manufactured, imported, supplied or sold wholly or principally;

47.3 for administering to a human being;

47.4 for a therapeutic purpose.[59]

48. The defendant says that although the chemicals are a substance, and they are used in water fluoridation for public health reasons (and therefore arguably for a therapeutic purpose as defined in the Act) given the context they cannot be said to be manufactured or supplied for *administering* to a human being for that purpose.

49. "Administer" is defined in s 2:

> **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

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58 "Substance" is defined as "any natural or artificial substance, whether in solid or liquid form or in the form of a gas or vapour" under s 2. "Article" is not defined and will have its ordinary meaning of object or item.

59 Defined in s 4 and includes in (a) "preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect, or injury".

> dissolved or IN (A) dispersed in, or diluted or mixed with, some substance in which it is to be administered

50. To come within the definition of "administer", the chemicals must be administered to a human being.

51. Dictionary definitions of administer include:

51.1 to give or apply (medicine, etc);[60] and

51.2 dispense (a drug or remedy).[61]

52. The addition of fluoride chemicals for water fluoridation does not amount to the giving or dispensing that is administering of these substances to a human being as contemplated by the Act. The context is such that it is simply inapt to apply the term "administer."

53. HFA and SSF in their undiluted form cannot be administered to a human being for a therapeutic purpose, as that would be harmful to health. Rather the compounds can only be administered to humans for a therapeutic purpose once they have been added to water. It is fluoridated water that is the substance in which the plaintiff says these medicines are administered. However, in this diluted form the resulting substance, fluoridated water, is not a medicine and the plaintiff does not dispute that point.[62] It is illogical and absurd to find that the compounds prior to dilution are a medicine but afterwards are no longer one.

54. Whilst the fluoride compounds are being diluted in water to an acceptable level, in a broad sense consuming fluoridated water or using it on your body to wash is not in a medicinal dose form required to be administered to human beings in the sense contemplated by the Act. It is simply not the same as diluting a pill in a glass of water where that pill is in an ingestible dose form. There are no corresponding labels, or instructions for use, or advice about how fluoride compounds that are added to water are to be consumed.[63]

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60 *Collins Concise Dictionary* (5th ed, HarperCollins, Glasgow, 2001).

61 Judy Pearsall (ed) *The Concise Oxford Dictionary* (10th ed, Oxford University Press, New York, 1999).

62 Plaintiff's submissions at [82].

63 Dr Jessamine does not consider consumption of water to constitute administration of a medicine. Refer to his affidavit at [27].

55. In *New Health* it was held that although the process of fluoridation is undertaken for a therapeutic purpose[64] it could not be relevantly distinguished from the addition of chlorine or any other substance for the purpose of disinfecting drinking water. This was because both processes involve adding a chemical compound to water and both are undertaken for the prevention of disease.[65] It was not material that one works by adding something to the water while the other achieves its purpose by taking unwanted organisms out.[66] The Court noted one would not naturally describe a person drinking fluoridated water as "undergoing" treatment.[67] Accordingly, it was held that water fluoridation was not medical treatment for the purposes of s 11 of NZBORA as that right is only engaged when the treatment takes place in a different context (a therapeutic relationship in which medical services are provided to an individual.[68]

56. The requirements of the purposive element of s 5(1) allows a strained interpretation to be put on words if the purpose of the provision requires it, provided it is an interpretation the words can legitimately bear. The defendant says that even if the term "administering" as used in 3(1)(a) could arguably be interpreted as applying to the water fluoridation process that is a strained interpretation which is inconsistent with the purpose of the Act.

57. The plaintiff relies on *McColl v Strathclyde Regional Council*[69] where the Scottish Court of Session held fluoride in whatever form falls within the definition of the Medicines Act 1968. This decision is not authoritative. It concerns a different act and there is only brief discussion on the point, with no consideration at all being given to the "administration" issue.

Context and statutory purpose inconsistent with HFA and SSF being a medicine

58. In any event, the context in which HFA and SSF are used means they are outside of the purpose of the Act. Therefore the "context otherwise requires" as does s 5(1) of the Interpretation Act 1999 that these chemicals do not come within the definition of a medicine.

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64 *New Health New Zealand Inc v South Taranaki District Council* [2014] NZHC 395, [2014] 2 NZLR 834 at [79].
65 Ibid at [80].
66 Ibid at [80].
67 Ibid at [82].
68 Ibid at [84].
69 *McColl v Strathclyde Regional Council* [1983] SC 225.

Context otherwise requires

59. The definition of "medicine" in s 3 is prefaced with a common statutory phrase "in this Act, unless the context otherwise requires, the term medicine means…".

60. When assessing whether fluoridated water constitutes a medicine the context and the statutory purpose require a different interpretation. The context in this case consists of the controls placed on the fluoridation of water in New Zealand under legislation and regulations.

61. The commonly used phrase "unless the context otherwise requires" indicates there may be occasions where it does not bear its defined meaning. There is however high threshold before the statutory meaning is displaced.[70]

62. Discussing the case law on this statutory phrase, the learned authors of *Statute Law in New Zealand* observe that "context" is given a wide meaning by the courts.[71] It includes not only the text of the provision in question, but also the purpose and policy of the legislation, its history, and the consequences of a suggested interpretation.[72]

63. Whilst in the leading case *Police v Thompson* the Court of Appeal found there was nothing in the context or the policy of the Act in question that pointed towards the wide statutory definition being applicable, in other cases Court have found the context to be sufficiently compelling to require departure from the statutory definition.[73]

64. As noted in *R v L*[74] in respect of the phrase:

> "The context can include the policy of the Act and the history of the legislation and the consequences of a given interpretation as well as the text surrounding the provision under examination: *Police v Thompson* [1966] NZLR 813, per Turner J at 820-1. Additionally, having regard to s 5(1) of the Interpretation Act 1999, a consideration of whether the

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70 Legislation Advisory Committee *Guidelines on Statutory Interpretation* (May 2001) at Chapter 3A.

71 JI Burrows and RI Carter *Statute Law in New Zealand* (4th ed, LexisNexis, Wellington, 2009) at 422.

72 See in particular *Police v Thompson* [1966] NZLR 813 (CA) at 820 per Turner J, and *Kirk v Electoral Commission* [2008] 3 NZLR 125 (HC) at [116] per MacKenzie J.

73 *Auckland City Corporation v Guardian Trust and Executors Co of New Zealand Ltd* [1931] NZLR 914 (SC) – the Court held the statutory definition was displaced by the injustice its application would cause and was supported by the underlying purpose of the provision. See also *Thompson v Wakapuaka Drainage Board* [1929] NZLR 548 (CA); *Re McLachlan's License* [1931] NZLR 651 (SC); *Skeet and Dillon v Nichols* (1911) 30 NZLR 122 (CA) *Harris v Hutton* (1914) 33 NZLR 1176 (SC); *Munro v R* [1971] NZLR 122 (CA); *Beck v Beck* [1975] 2 NZLR 123 (SC); *Crusader Fisheries ltd v Eno (Maritime New Zealand)* HC Wellington CRI-2007-442-5, 11 December 2007 per Wild J; and *R v L* HC Wellington CRI-2007-485-159, 11 April 2008 per MacKenzie J.

74 *R v L* HC Wellington CRI-2007-485-159, 11 April 2008 per MacKenzie J.

> context requires a departure from a defined term must be undertaken in the light of the purpose of the provision in question."

65. Here, the defendant says if the Court considers HFA and SSF can be interpreted to fall within the definition of medicine in s 3(1)(a), the context requires a departure from the definition. Such a departure would be consistent with the policy and scheme of the Medicines Act and would avoid an interpretation that would lead to impractical and unworkable consequences.

66. The consequences of interpreting the Act as the plaintiff suggests would mean manufacturers of HFA and SSF to be licensed under the Act (s 17), to obtain Ministerial approval under s 20 and be subject to other relevant requirements of the Act and Regulations. These may include, for example, meeting labelling requirements, restrictions on advertising and record keeping.

Context, purpose and scheme of the Act

67. The purpose of the Act is to ensure that medicines and medical products are safe and effective for use by consumers (as outlined more fully above at [25]-[30]).

68. The regulation of community water fluoridation does not properly fit within that purpose. Fluoride compounds have never been considered to be properly within the ambit of the Medicines Act, for good reason. Access to and provision of a safe water supply is required under regulation in New Zealand and essential as a public health measure. Parliament could not have intended that public health measures regulated under different regimes, such as fluoridation of the water supply, would also constitute a medicine.

69. The safety, quality and efficacy of water fluoridation is already (and is more appropriately) controlled under other legislation (including the Health Act 2002), policy, industry standards and guidelines that are outlined above at [11] – [24] and do not need repeating here.

70. There is no suggestion by the plaintiff that those controls and standards do not sufficiently protect the public from any health risks and no useful purpose or public interest would be served by HFA and SSF coming within the definition of medicine in the Act.

71. Water fluoridation has been safely undertaken in New Zealand for over sixty years and would be an absurd result to now require licenses and or consents to be obtained and the labelling requirements, and so as prescribed under the Medicines Act. To be complied with.

72. The context of the Act and Regulations points against the interpretation contended for by the plaintiff. Regulations already prescribe when fluoride is considered a medicine when it is of a sufficient concentration. As outlined above at [44], fluoride in certain concentrations and formulations is scheduled as a medicine in several schedules within the Act, however the concentrations of fluoride in drinking water is well below the threshold for consideration as a medicine under the Regulations. Fluoride is an element and it is naturally found in water in New Zealand, the presence of fluoride, or any other element or mineral (notwithstanding it being a scheduled substance) in an item does not in and of itself make the item a medicine.

73. Further, there are specific permissions for fluoridated water provided under the regulations that accompany the Food Act 1981. The Food (Safety) Regulations 2002 (promulgated under s 42 Food Act 1981) relevantly provide for fluoridated water to be added to food when fluoridated to levels permitted under the Health Act 1956.[75]

Purposive, pragmatic and common sense interpretation required

74. As well as a purposive interpretation being required by s 5(1) of the Interpretation Act the Court should apply a pragmatic and common sense approach to the interpretation of the definition in order to ensure the section is workable.

75. The Court should presume that the legislator intended common sense to be used in construing the enactment.[76] There is also a presumption that an absurd result cannot have been intended. The Courts give "absurd" a far wider definition than ordinary English, meaning out of harmony with reason or propriety; incongruous, unreasonable, illogical.[77] Court's will similarly seek to

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75 Food (Safety) Regulations 2002, Part 2, reg 24.

76 Oliver Jones *Bennion on Statutory Interpretation: A Code* (6th Ed, LexisNexis, London, 2012), section 197, at 511. In *Barnes v Jarvis* [1953] 1 WLR 649, per Lord Goddard CJ at 652 it was noted that "a certain amount of common sense [must be applied] in construing statutes".

77 *Bennion* at section 312, at 869. This presumption has been endorsed by the House of Lords in R *(on the application of Edison First Power Ltd) v Central Valuation Officer*), where Lord Millett stated: "The courts will presume that

avoid a construction of an enactment that produces an unworkable or impracticable result, since this is unlikely to have been intended by Parliament.[78]

76. The broad scope of the definition means a pragmatic view of the section must be taken, in order to ensure the section is workable. The importance of a pragmatic, contextual interpretation is emphasised by Dr Jessamine in his evidence. The concern is that if the plaintiff's interpretative approach was adopted, any number of substances/articles may inappropriately fall to be regulated under the Act.[79] This would lead to consequences that Parliament could not have intended when enacting the Medicines Act.

Conclusion

77. This application for declaratory orders should be dismissed.

78. The defendants seek costs on a 2B basis.

26 September 2014

Jane Foster/Maria Clark
Counsel for the defendant

Parliament did not intend a statute to have consequences which are objectionable or undesirable; or absurd; or unworkable or impracticable; or merely inconvenient; or anomalous or illogical; or futile or pointless. But the strength of these presumptions depends on the degree to which a particular construction produces an unreasonable result. The more unreasonable a result, the less likely it is that Parliament intended it..."

[78] *Bennion* at 870. In *R v Deputy-Governor of Camphill Prison, ex p King* [1985] QB 735, at 751 Griffiths LJ stated: "The common law of England has not always developed along strictly logical lines, and where logic leads down a path that is beset with practical difficulties the court have not been frightened to turn aside and seek the pragmatic solution that will best serve the needs of society."

[79] Affidavit of Stewart Sinclair Jessamine at [25]-[34]