IN THE HIGH COURT OF NEW ZEALAND
NEW PLYMOUTH REGISTRY

CIV 2013-443-107

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	SOUTH TARANAKI DISTRICT COUNCIL
	Defendant

AFFIDAVIT OF STEWART SINCLAIR JESSAMINE

13 September 2013

Judicial Officer: Heath J
Next Event Date:

CROWN LAW
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I, Stewart Sinclair Jessamine, of Wellington affirm:

1. I am a registered medical practitioner, New Zealand Medical Council registration number 14997. I live in Wellington and have been employed as a Medical Advisor with responsibility for assessing the safety, quality and efficacy of medicines since March 1993. Since 2007 I have been employed as the Group Manager of Medsafe, (New Zealand Medicines and Medical Devices Safety Authority), the regulatory authority responsible for administering the New Zealand Medicines Act 1981 and Regulations.

2. I graduated MB ChB from Glasgow University in 1981. Following graduation I underwent training in General Medicine for a period of 4 years before entering a 2 year training programme for General Practice. I emigrated to New Zealand in 1987 and worked as a General Practitioner in rural New Zealand until accepting in a position with the Department of Health in 1993. I am a Fellow of the Royal Australasian College of Medical Administrators (RACMA) and am registered with the Medical Council as a specialist in that field. I also hold post-graduate qualifications including a Diploma in Obstetrics and Gynaecology, obtained from the University of Auckland and a Masters in Public Health obtained from the University of Otago.

3. During my term of employment at Medsafe I have been involved in performing a number of duties including the evaluation of the clinical information supplied by a medicine sponsor in an application seeking Ministerial consent to market a medicine in New Zealand under the Medicines Act. I have been a member of several Ministerial advisory committees including the Medicines Adverse Reaction Committee which monitors the safety of medicines, and I am chairperson of the New Zealand Medicines Classification Committee which makes assessments and recommendations on which medicines should be prescription only and which can be made available over-the-counter. I also am required to give specialist advice on clinical issues relating to the safety and efficacy of medicines to the Ministry of Health and have provided expert opinion on the Medicines Act in a number of legal hearings.

4. Medsafe is the New Zealand Medicines and Medical Devices Safety Authority. It is the regulatory body responsible for the regulation of medicines and

medical devices in New Zealand through administration of the Medicines Act 1981 and Medicines Regulations 1984.

5. The Medicines Act 1981 defines and controls medicines, medical devices, and related products and to some extent cosmetics. The purpose of all these controls is the protection of public safety. The Act therefore defines what is a medicine and places controls on the distribution of medicines, the places where medicines may be manufactured, (through a licensing system) the importation and distribution of medicines, as well as quality standards for medicines and for packaging.

6. 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 the standards claimed for them, or if they are used unwisely or inappropriately.

7. The overarching intention of the Medicines Act 1981, and Medsafe, is the protection of public safety through minimisation of the risks associated with utilising a pharmaceutical product (a medicine).

8. The defendant has asked me to set out Medsafe's position on whether water fluoridated to increase the level of fluoride to 0.7- 1.5 parts per million (ppm) (the range of acceptable fluoridation levels in New Zealand) constitutes a medicine and the reason why Medsafe has concluded that, for the purposes of the Medicines Act 1981, water fluoridated to this level is not properly considered to constitute a medicine.

9. I have read, and agree to comply with, the Code of Conduct for Expert Witnesses set out in Schedule 4 of the High Court Rules.

10. I understand that I have an overriding duty to assist the Court impartially on relevant matters within my expertise.

11. I confirm that the issues my evidence addresses are within my area of expertise. I also confirm that I have not omitted to consider material facts which might influence the opinions stated in this evidence.

Medsafe View on Status of Fluoridated Water

12. A medicine is defined in section 3 of the Medicines Act 1981 as:

> (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.

13. Section 4 defines the term "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.

14. Medsafe has never considered the fluoridation of water, to the levels prescribed in New Zealand, to lead to the creation of a medicine. Fluoride in certain concentrations and formulations is scheduled as a medicine in several places within the first schedule of the Medicines Act. However, the

concentrations of fluoride in drinking water are well below the minimum default threshold in the first schedule of the Act for consideration of a substance as a medicine of 10mg/kg (equivalent to 10ppm). Indeed, s58A of the Medicines Regulations 1984 makes it clear that fluoride is not considered to be a medicine, or a related product, even when it is included in toothpastes or dentifrices that contain 15 milligrams or less per litre or per kilogram of fluoride i.e. at concentrations 10 times higher than that found in water.

15. In defining what amounts to a medicine it is not sufficient to say that a substance has medicinal qualities. Fluoride is an element found naturally in water at varying concentrations, the presence of fluoride or any other scheduled element or mineral in an item does not of itself make the item a medicine. Lithium can be used as a medicine, and is included in the first schedule of the Medicines Act, but its presence in a lithium battery or a paint, for example, does not make that product a medicine.

16. Nor is it sufficient that a substance has therapeutic qualities. While quinine is a medicinal substance, the quinine contained in a gin and tonic, no matter how therapeutic we might think consuming one may be, does not make tonic water (or gin) a medicine. The same can be said for margarine substitutes that contain plant sterols and claim to lower cholesterol, or high fibre breads, they are all foodstuffs, not medicines. A degree of practicality is required in determining that a substance is medicinal. Too rigid an interpretation of "medicine" quickly makes everything a potential medicine. After all, we drink water to prevent dehydration which is a symptom of a disease state.

17. As set out above, under the Medicines Act a substance is not a medicine unless it is supplied wholly or principally for a therapeutic purpose. Drinking water- even drinking water with enhanced levels of fluoride- is not supplied for a therapeutic purpose. The principal use of drinking water is dietary. Medsafe therefore does not consider the addition of fluoride- or of other substances commonly added to water, such as chlorine or alum- to result in water falling under the remit of the Medicines Act. Rather, treated water supplies are more

properly regulated by public health and water quality legislation.

AFFIRM

at Wellington this 13th day of September 2013)
before me:)
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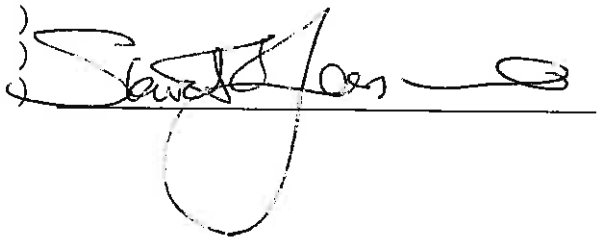

A Solicitor of the High Court of New Zealand

Richard Terence Charles Brandon
Solicitor
Wellington