Barristers.Comm • Level 8 Wakefield House • 90 The Terrace
PO Box 8045 • Wellington 6143 • New Zealand • T +64 4 914 1052 • F +64 4 473 3179
M 021 0241 3822 • E l.hansen@barristerscomm.com

LISA HANSEN
BA(Hons)LLB(Hons) Otago
BARRISTER

24 December 2014

Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection and Regulation
Ministry of Health
P O Box 5013
WELLINGTON

Dear Sir

SUBMISSION BY NEW HEALTH NEW ZEALAND INC

Summary

The proposal

1. The proposal is that a new regulation be made under s 105(1)(i) of the Medicines Act 1981 that:

> Fluoride-containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purposes of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies.

2. Two questions are posed:

> *Question 1: Do you support the proposed amendment? If not, why not?*
>
> *Question 2: Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

Response to Question 1

3. New Health NZ Inc does not support the proposed amendment for the following reasons:

   3.1. A regulation is premature and should await the outcome of the Court of Appeal decision in *New Health NZ Inc v Attorney-General.*

3.2. The regulation is an improper attempt to pre-empt the Court of Appeal's consideration of whether HFA and SSF are medicines.

3.3. The consultation document makes no reference to the appeal and is misleading as to the true rationale for the proposal. It should have referred to the appeal and expressly stated that a purpose of the exemption was to avoid the Court of Appeal determining that HFA and SSF are medicines.

3.4. The purpose of s 105(1)(i) of the Medicines Act 1981 is to declare substances that would otherwise be medicines not to be medicines. The power is exercised on the assumption that the substance is a medicine but that there is no need for the Medicines Act provisions to apply. The consultation document does not proceed on this basis and is flawed. On the assumption HFA and SSF are medicines, there is no rational or proper basis to exempt them from the Medicines Act. To the contrary, there are compelling reasons why they should be subject to the protections of the Act.

3.5. The consultation process is flawed. Insufficient information about the true reason for the proposal has been provided, the proposal fails to address the propriety of exempting these substances if they were medicines, and insufficient time has been provided to the public to respond.

Response to Question 2

4. No. The reference to treating water supplies is misleading. Water fluoridation is not a water treatment process. The only purpose of water fluoridation is therapeutic, ie to treat people, not water.

Summary of the High Court decision and grounds of appeal

5. In its decision dated 9 October 2014, the High Court held that HFA and SSF when added to domestic water supplies in NZ to produce fluoride concentrations up to 1.5 mg/l are not medicines within the meaning of the Medicines Act 1981 (*New Health NZ Inc v Attorney-General*).

6. 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.

7. The judge found that HFA and SSF satisfied all of the key elements of the definition of a medicine. He held that they were administered for a therapeutic purpose, namely the prevention of tooth decay, and that they achieved their intended action on human beings by a pharmacological process: paragraphs [14] to [39].

8. However, the judge found that the context, namely the Medicines Regulations 1984, required a different interpretation.

9. The judge reasoned:

6.1. the concentration threshold for substances to be medicines in Schedule 1 of the Medicines Regulations 1984 is 10 mg/l; and

6.2. the concentration of fluoride in domestic water supplies is no more than 1.5 mg /l; then

6.3. fluoride would only be a medicine under the Act if it was added to domestic water supplies in concentration of 10 mg/l or more.

(refer paragraphs [45] to [50] of the judgment)

10. The judgement is under appeal. A hearing is to be held on 12 March 2015.

11. New Health raises three grounds of appeal. First, the judge made a basic error of statutory interpretation when he used the Medicines Regulations to read down a definition in the parent Act.

12. Secondly, the judge misconstrued the Medicines Regulations and Schedule 1 in particular. Schedule 1 does not define what is or is not a medicine per se. What this Schedule does is classify the particular medicines listed as either prescription medicines, restricted medicines or pharmacy-only medicines: refer regulation 3.

13. Schedule 1 is not an exhaustive list of medicines.

14. The prefatory words in the Schedule 1 state:

> Unless specific reference is made otherwise, every reference to a medicine in this schedule applies –
> ....
> If the medicine is not an injection or eye preparation, only if the concentration of the medicine is greater than 10 milligrams per litre or per kilogram.

15. This means that medicines listed in the Schedule that do not specify a concentration, are only prescription medicines, pharmacy-only medicines or restricted medicines if they are at a concentration of more than 10 milligrams per litre.

16. However, they are still medicines at concentrations less than 10 milligrams per litre.

17. The judge wrongly interpreted the Schedule to mean that the substance is not a medicine unless its concentration is more than 10 milligrams per litre. This interpretation is contrary to the plain words of the Medicines Regulations and Schedule 1.

18. Thirdly, as set out in the judgement at footnotes 20 to 22 of the judgment, fluoride is classified in various preparations as a prescription medicine, pharmacy only medicine and restricted medicine in Schedule 1. Contrary to the judge's approach, the prefatory words in the Schedule do not apply to fluoride because "specific reference" has been made to define when fluoride is a prescription, pharmacy-only and restricted medicine. Put another way, the default concentration of more than 10 milligrams per litre does not apply to fluoride in order for it to be a pharmacy-only, prescription or restricted medicine.

19. The judge appears to have overlooked that fluoride is a general sale medicine at 15 milligrams or less per litre: refer footnote 23 of the judgment. That concentration captures the concentration of HFA and SSF in drinking water.

Scope of the exemption power

20. Section 105(1)(i) of the Medicines Act empowers the Governor-General to make a regulation "specifying, by name or description, substances or articles, or kinds or classes of substances or articles, that are, or are not medicines for the purposes of this Act".

21. The definition of a "medicine" in s 3 excludes "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".

22. The purpose of s 105(1)(i) of the Medicines Act 1981 is to declare substances that would otherwise be medicines not to be medicines. The power is exercised on the assumption that the substance is a medicine but that it is not appropriate for the Medicines Act provisions to apply.

23. To date the power has been exercised in relation to dentifrice products, anti-dandruff hair products, anti-acne skin products, barrier creams and anti-bacterial skin products. Regulation 58A of the Medicines Regulations exempts these products from being medicines or related products provided they don't contain medicines specified in Schedule 1 (ie pharmacy-only, prescription and restricted medicines) and only claim certain limited therapeutic purposes.

24. These products were exempt on the bases that they were relatively low risk products and that the Cosmetic Products Group Standard adequately protected consumers.

Improper exercise of exemption power

25. New Health raises the following concerns with the proposed exercise of the exemption power.

26. First, the regulation is premature.

27. Presently the Minister has the benefit of the High Court's finding that HFA and SSF are not medicines. No regulation to exempt them from being medicines is required.

28. The proposed regulation is an improper attempt to pre-empt New Health's appeal. Subordinate legislation should not be used in that way.

29. Unless New Health wins the appeal, there is no need for the regulation. If New Health succeeds on appeal, the Minister can then address whether HFA and SSF should not be medicines. By promoting a regulation now, the Minister is seeking to avoid exempting HFA and SSF on the basis that they are medicines.

30. The reference in the discussion document to the regulation providing "greater clarity about the issue by removing any possible ambiguity" is spurious as "clarity" was provided by the High Court. The true reason for the exemption is to pre-empt the appeal. The consultation document

is flawed by failing to refer to the existence of the appeal and the potential consequences of the High Court's decision being overturned.

31. Secondly, the Minister is proceeding on the basis that HFA and SSF are not medicines and that he is merely regularising the status quo. This is not the proper basis on which to exercise the power.

32. The correct approach is to assume that a substance is or is likely to be a medicine but that it not necessary that it is subject to the Medicines Act. The discussion document does not proceed on this basis or address considerations such as the relative risk of the substances or whether there are sufficient protections for the public if these substances are not regulated as medicines.

33. Thirdly, the proposal is an unusual exercise of the power. The proposal is to exempt HFA and SSF from being medicines "when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies".

34. Section 105(1)(i) permits substances to be specified by name or description or kinds or classes, not to be medicines.

35. The purpose of the provision is that particular substances or articles are either a medicine or not.

36. The proposal that HFA and SSF when put in the water supply are not medicines, but might otherwise be medicines if put in tablets for example appears contrary to that purpose.

37. It also raises the question why HFA and SSF should not be exempt in all applications and delivery mechanisms when used to prevent dental decay. Why limit the exemption to use in water fluoridation.

38. The proposal also implies that sodium fluoride tablets (which a pharmacy-only medicine) could suddenly be supplied exclusively for water fluoridation and in that form not be medicines. If that were seriously contemplated, the Ministry would need to carefully explain the rationale for such an approach.

Exemption cannot be justified if HFA and SSF medicines

39. To reiterate the regulation making power should proceed on the assumption that HFA and SSF are medicines. The question then is whether it is appropriate that they are not subject to regulation under the Medicines Act. This would include considering the risks of the substance and whether sufficient protections for consumers are available outside the Medicines Act.

40. For the reasons set out below there are compelling reasons why these substances as medicines should be subject to the controls of the Medicines Act.

41. It is incontrovertible that HFA and SSF are being used as an alternative to sodium fluoride tablets. One litre of water fluoridated at 1 ppm contains 1 mg of fluoride. That is the same amount of fluoride as two pharmacy-only sodium fluoride tablets.

A comparison of HFA/SSF and sodium fluoride tablets is set out in the table below.

	Sodium fluoride tablets (pharmaceutical grade)	**HFA and SSF (industrial waste)**
Claimed Purpose	Prevent tooth decay	Prevent tooth decay
Status	Medicine: Pharmacy-only medicine (ie illegal to be supplied by councils) subject to purity and other manufacturing standards set out in Medicines Act and Regulations	Hazardous substance: Toxic by-product of the superphosphate industry that may also contain arsenic, mercury and lead.
Concentration	Each tablet contains 0.5 mg of fluoride	Up to 1 mg of fluoride per litre of water
Recommended Maximum Dose of Fluoride	Not to be taken by children under 3 or during pregnancy. 3 to 5 years: half a tablet daily 6 to 8 years: 1 tablet daily Adults: Two tablets daily.	Dose is uncontrolled and depends on how much water is drunk by each individual. Many children and adults will exceed maximum daily recommended medicinal doses. Babies, toddlers, and pregnant women should not be drinking fluoridated water.
Informed consent	Yes	No

42. Sodium fluoride tablets and HFA and SSF are identical in terms of therapeutic purpose and effect. They are being used to prevent tooth decay and have the same pharmacological mechanism of action. Sodium fluoride tablets have been assessed to be of sufficiently high risk to be pharmacy-only medicines.

43. There is no justification for sodium fluoride tablets being regulated as medicines and subject to the quality, safety and efficacy requirements of the Medicines Act, but not HFA and SSF.

44. First, if sodium fluoride tablets are subject to the purity and manufacturing requirements of the Medicines Act, so too should HFA and SSF. HFA and SSF are heavy-metal contaminated toxic industrial waste products. These substances should not be permitted to be used on whole populations when there have been no reports of tests or clinical trials made to establish their safety and efficacy.

45. Secondly, there is the issue of dose. All medicines must be delivered in a dose form and have a specified maximum dose. Sodium fluoride tablets have a maximum stated dose for an adult of two tablets which is 1 mg of fluoride. Fluoride tablets should not be taken by babies, toddlers and pregnant women. There is no justification for the Ministry stipulating a maximum dose of fluoride for sodium fluoride tablets but permitting the same active ingredient to be delivered in uncontrolled doses through water fluoridation.

46. Many people will consume more fluoride through fluoridated water than is the recommended daily dose for an adult consuming sodium fluoride tablets. The potential risks of systemic over-exposure to fluoride are well documented. These risks include dental fluorosis, skeletal fluorosis, bone fracture, bone cancer, lowered IQ, kidney and thyroid dysfunction, and gastrointestinal problems. By failing to control the dosages of fluoride delivered through water fluoridation, the Ministry is potentially jeopardising the health of New Zealanders.

47. This is particularly so for babies and infants and toddlers who drink water or formula made with fluoridated water. With no or few teeth they derive no benefit from fluoridated water but depending on how much they drink, may be susceptible to fluoride poisoning in the form of dental fluorosis.

48. The Ministry doesn't permit any other medicine to be administered in uncontrolled doses, and HFA and SSF should not be treated any differently.

49. Thirdly, water fluoridation trespasses on personal rights and liberties. Contrary to ethical medicine delivery principles, HFA and SSF are administered to populations without informed consent.

50. The Ministry needs to explain why in respect of the provision of these medicines, informed consent can be overridden when that tenet is fundamental to the administration of all other medicines.

51. As a final but separate point it is noted that the prior use of the exemption power has been restricted to topical substances, such as hair and skin products and dentifrices.

52. The current proposal relates to medicines that are to be swallowed.

53. If a systemically ingested medicine is to be exempt, it should be on the basis of compelling evidence that the medicine worked systemically.

54. The scientific evidence, is clear that to the extent fluoride provides any benefit against tooth decay, its effect is primarily topical. The effect of ingested fluoride on dental decay is minimal and this point is not seriously contested. It is also not seriously in dispute that the concentration of fluoride in ductal saliva is too low to have any cariostatic effect.

55. It raises the question of why people should be required to swallow fluoride via water fluoridation when any benefit is provided topically. You don't drink sunscreen to provide protection for your skin.

56. Tellingly the Ministry in its discussion document acknowledges that "there is no universal acceptance of the positive health effects of the addition of fluoride to drinking water supplies": This is a welcome concession by the Ministry. It also demonstrates that the recent Gluckman/Skegg report which refused to consider the scientific evidence on efficacy on the grounds that there was "a clear consensus on the effectiveness of CWF", was wrong.

Second question

57. In its discussion document the Ministry refers to fluoride substances used to "treat drinking water".

58. That phrase is inapt and spurious. Fluoride is not a water treatment agent. It is being put in the water solely to treat people.

59. HFA and SSF when used to prevent dental decay and when used in any manner, not just in water fluoridation, should not be exempt from the Medicines Act, and neither should any other so-called water fluoridation substance.

Consultation timeframe too short

60. New Health objects to the limited timeframe for making submissions and the fact that submissions are due so early in the New Year.

61. The timeframe is unreasonable and the submission period should have closed around early to mid February 2015. Under the Official Information Act the period 25 December to 15 January is excluded from the time within which officials are required to respond to requests for information. Submitters should not be expected to provide a response within this period either. Many people will still be on holiday.

Proper way for the Ministry to proceed

62. The proposal and process are flawed and open to challenge.

63. New Health says that the following should occur:

    a. The Ministry withdraws the proposal.

    b. Any new proposal proceeds on the following basis: that a regulation is only required if the Court of Appeal determines HFA and SSF are medicines; the Ministry fully explains in the consultation document why, if HFA and SSF are medicines, they should nonetheless be exempt from the Medicines Act.

    c. The appeal is heard and determined.

64. For completeness New Health's view is that the Minister could not responsibly promote an exemption on the basis that HFA and SSF are medicines. If the Ministry actually confronted the proposition that HFA and SSF were medicines it would not be able to explain why fluoride tablets must be pharmacy-only medicines but that HFA and SSF can be immune from the protections of the Medicines Act. A regulation must not be a mechanism to rubber stamp a flawed Ministry of Health policy, and some Councils' practice of the past.

Request to be heard orally

65. New Health wishes to be heard in support of its submission. Counsel is away until 26 January 2015 but would be available from 27 January onwards.

Yours sincerely

Lisa Hansen