Proposed Amendment to Regulations under the Medicines Act 1981
Report of the Analysis of Submissions

February 2015

Introduction

On 25 November the Ministry of Health (the Ministry) released a consultation document *Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 (the Act).* Feedback on the proposal was sought by 9 January 2015.

The Ministry's position is that: fluoridation of community water supplies, which has been occurring in New Zealand since 1955, is legal and permitted by Part 2A of the Health Act 1956; that the water quality standards required by this legislation are sufficient to protect the public health from harm; the chemicals used to fluoridate water supplies are covered by the Hazardous Substances and New Organisms Act 1996; and finally that the Medicines Act 1981 (the Medicines Act) does not apply to either the chemicals used to fluoridate drinking water, or to the consumption of fluoridated community drinking water.

Following recent litigation on the legal status of fluoride, Justice Collins at the High Court issued a judgement supporting the Ministry's position and found Hydrofluorosilicic acid (HFA) and Sodium silicofluoride (SSF), the chemicals routinely used at water treatment plants to fluoridate domestic drinking water supplies, are not medicines within the meaning of "medicine" under the Medicines Act. In his judgement, Justice Collins recommended use of regulation-making powers under the Medicines Act to exempt HFA and SSF from being medicines for the purposes of the Medicines Act to provide greater clarity about the status quo regarding the use of HFA and SSF in water fluoridation.

The Ministry is proposing to make a new regulation, principally under section 105(1)(i), to provide that:

> *Fluoride-containing substances, including the substances HFA and SSF are not medicines for the purposes of the Medicines Act when they are manufactured and supplied or distributed for the purpose of fluoridating community drinking water supplies.*

The scope of the consultation did not cover any policy or process relating to the fluoridation of community water supplies.

The consultation document sought comment on two questions:

- 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?

The Ministry of Health received 1387 submissions from a wide cross-section of the community. Of these, 47 submissions were received from health professionals, 18 from health organisations, 18 from organisations with an interest in the subject and the balance from members of the public.

Summary of responses to Question 1

Submissions in support of the proposal

Seventy-two submissions supported the proposed amendment. Of these submissions 33 were from members of the public, 18 from health professionals and 18 from health organisations. The balance was from groups with an interest in fluoridation of community water supplies. In general these submissions agreed that there were no outstanding safety issues associated with fluoridation, that fluoridation of drinking water delivered substantial public health gain by reducing the rate of dental caries, and that the existing controls in the Health Act 1956 which determine the limit of fluoride that can be added to drinking water were sufficient to protect the public from harm.

Submissions that opposed the proposal

1315 submissions do not support the proposal: 29 from health professionals, 15 from groups with an interest in the fluoridation of community water supplies and the balance from members of the public.

Of the submissions not in support of the amendment, 82% were in the form of standard letters.

There were a range of reasons for opposing the proposal:

(a) **Fluoride is a medicine.**

These submissions essentially present the same arguments argued before Justice Collins and subsequently rejected by His Honour in the High Court in *New Health New Zealand Inc v Attorney-General* (2014). The underlying assumption in these submissions is that the proposed amendment is fundamentally changing the legal status of fluoride. This is not the case. The amendment is simply clarifying the existing legal status, ie, that the chemicals used to fluoridate drinking water, and fluoridated drinking water itself are not considered to be medicines. Accordingly, no change to the proposed regulation is required.

(b) **Fluoride is a toxic substance and consumption of fluoridated drinking water is associated with a range of diseases and adverse effects and the proposed exemption undermines the purpose of the Medicines Act to protect public health.**

These submissions argue that fluoride is poison which can produce adverse effects at the concentrations added to community drinking water supplies. The submissions also state that there is evidence that exposure to fluoridated drinking water is associated with cardiovascular disease, cancer, and neurological damage leading to a fall in IQ. In the opinion of the submitters, this risk is compounded by the fact that the dose of fluoride consumed in drinking water varies from person to person and so is essentially uncontrolled and the chemicals used to fluoridate drinking water also contain other dangerous chemicals such as heavy metals.

In August 2014, shortly before Justice Collins heard the case arguing that fluoride was a medicine, a report titled *Health Effects of Water Fluoridation: A review of the scientific evidence* (the report) was released. The report was jointly authored by the Royal Society of New Zealand and the Office of the Prime Minister's Chief Science Advisor. The report was written and peer reviewed by a New Zealand panel of scientific experts and represents an overview and critique of the available published data on fluoridation of drinking water.

The report (attached as Appendix 1) considered in-depth peer reviewed, published scientific papers on fluoride and fluoridation of drinking water including the issues raised in the submissions. The covering letter which accompanies the report states:

> *"Given the caveat that science can never be absolute, the panel is unanimous in its conclusion that there are no adverse effects of fluoride of any significance arising from fluoridation at the levels used in New Zealand. In particular, no effects on brain development, cancer risk or cardiovascular or metabolic risk have been substantiated, and the safety margins are such that no subset of the population is at risk because of fluoridation"; and*
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> *"All of the panel members and ourselves conclude that the efficacy and safety of fluoridation of public water supplies, within the range of concentrations currently recommended by the Ministry of Heath, is assured. We conclude that the scientific issues raised by those opposed to fluoridation are not supported by the evidence."*

The public health value and importance of fluoridation of drinking water is perhaps best expressed by the United States Centre for Disease Control and Prevention (CDC) which recognises drinking water fluoridation as one of the 10 great public health achievements of the 20th century.

In respect to the view that the consumption of drinking fluoridated water can be regarded as an uncontrolled intake of a poison which can lead to toxicity, the report concludes that at the levels of fluoride found in New Zealand water supplies this claim is not supported by research, including local New Zealand research.

Research included in the report confirms that the total daily intake of fluoride (from water, toothpaste and food), for New Zealanders aged five years and above are below that determined to represent the intake of nutrients necessary for optimal health.

With respect to infants aged 0–12 months, the report concludes that infants exclusively fed on infant formula reconstituted with fluoridated water (at levels currently permitted in New Zealand), and infants drinking fluoridated water and brushing their teeth with fluoride-containing toothpaste are likely to be close to, or slightly exceed, the calculated conservative upper intake level for daily fluoride intake. The report however, notes that numerous authorities support the safety of using fluoridated water to reconstitute infant formula, and the use of small amounts of fluoride toothpaste in young children. The consensus expert opinion is that the benefit of exposure to fluoride in these children exceeds the small risk of minor fluorosis and cosmetic tooth mottling that may occur in association with consumption of fluoride in drinking water at the levels currently permitted in New Zealand.

(c) **Fluoridation of water is a form of mass-medication and is ineffective in preventing the development of dental caries.**

In the other High Court case taken by New Health New Zealand Inc. challenging the power of the South Taranaki District Council to legally fluoridate water supplies (*New Health New Zealand Inc v South Taranaki District Council* [2014] NZHC 395, Hansen J) the court concluded that addition of fluoride to the water supply was legal and permitted by the Health Act 1956, and that the delivery of fluoride in drinking water did not constitute mass-medication.

In addition, Justice Collins in his judgement determined that fluoride at the concentration found in community drinking water supply is a not a medicine.

In regards to the claim that fluoridation of drinking water is ineffective, the report is very clear in its conclusion that the benefits of fluoridation of drinking water outweigh its risks:

> *"There is compelling evidence that fluoridation of water at the established and recommended levels produces broad benefits for the dental health of New Zealanders. In this context it is worth noting that dental health remains a major issue for much of the New Zealand population, and that economically and from the equity perspective fluoridation remains the safest and most appropriate approach for promoting dental public health.'*

The report found no evidence of adverse effects of fluoridation of drinking water at levels used in New Zealand other than mild fluorosis, which is only of minor cosmetic significance. There is a substantial evidence base to indicate that the inappropriate use of dental products (eg, young children swallowing large amounts of toothpaste; inappropriate prescribing of supplements) is the main factor in increasing fluorosis risk, as the prevalence of fluorosis has increased more in non-fluoridated areas than in fluoridated ones. No severe form of fluorosis has ever been reported in New Zealand.

(d) **Jurisdictions outside of New Zealand do not fluoridate water or have banned water fluoridation**

This claim is not supported by substantiated evidence. The claim is discussed in the report and contrary to the submitters' claim, found that:

> *"Around 30 countries worldwide have intentionally fluoridated water supplies, serving an estimated 370 million people. An additional >50 million people drink water that is naturally fluoridated at or near the optimal level, including those supplied from some water sources in Canada, the UK, Spain, Japan, Finland, Chile, Argentina and Australia that have natural fluoride levels of around 1.0 mg/L"; and*
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> *"It is sometimes claimed that European nations have abandoned the practice of fluoridation; this, in fact, is not the case. As of 2014, the UK, Ireland, and Spain fluoridate their water, while other nations put fluoride in table salt or acquire it naturally from higher levels present in drinking water, as in Sweden and Italy. Most experiences gained through water fluoridation, accumulated over decades of epidemiological research, also apply to salt fluoridation. As with water fluoridation, salt delivers fluoride both systemically and topically, and is used in some areas where water fluoridation is not feasible. Approximately 70 million Europeans consume fluoridated salt, including most of the population of Germany and*

Switzerland ... For many European communities, salt is used because their complex water systems make water fluoridation impractical."

(e) **Exempting fluoride from the control of the Medicines Act removes individual choice and will allow local communities to proceed with fluoridation without consultation.**

The Medicines Act does not regulate fluoride added to community water supplies as a medicine. The proposed amendment simply clarifies the current legal situation. The consultation process that Councils are required to undertake to commence fluoridation of a community water supply is outside the scope of the Medicines Act. The proposed amendment will not consequentially amend or remove the need for a Council to consult on fluoridation. The proposed amendment also has no impact on the status quo with respect to individual choice to consume fluoridated drinking water. Consumers can continue to elect to not consume fluoridated community drinking water by collecting, or purchasing, alternate supplies of drinking water that do not contain fluoride.

(f) **Proceeding with the consultation process is legally unsafe until an appeal submitted arguing against Justice Collins' judgement is heard.**

In proposing to amend the Medicines Regulations to clarify that the chemicals used to fluoridate water and fluoridated water itself are not medicines, the Ministry is acting on the recommendation made by Justice Collins in his judgement. Amending the Medicines Regulations does not prevent or prohibit New Health New Zealand Inc. from appealing against Justice Collins' judgement to the Court of Appeal.

(g) **The Government should provide more education on the dangers of sugary foods and introduce taxation of sugar in foods.**

The Ministry of Health produces nutritional and dietary advice aimed at reducing the amount of sugar consumed in the New Zealand diet. While there is evidence that reduction of the consumption of sugary foods would contribute to improvements in dental health and obesity, this issue is outside the scope of the consultation document and the proposed clarifying amendment to the Medicines Regulations.

Outcome

The submissions raised a number of issues relating to the definition of medicine and the argument that fluoride is a medicine. The submissions restate and reiterate the argument already considered and rejected by Justice Hansen and Justice Collins in the High Court.

The submitters also made a series of statements about the toxicity of fluoride and their view that the risk of harm associated with consumption of fluoridated water outweighs any possible benefits. These claims are not supported by the 2014 review of the scientific evidence of the safety and efficacy of fluoride undertaken by the Royal Society of New Zealand and the Office of the Prime Minister's Chief Science Advisor. As that report represents the latest expert opinion on the safety of fluoride available and refutes the claims made by the submitters, no change to the proposed regulation is considered necessary.

Summary of responses to Question 2

Twelve submissions supporting the proposed amendment suggested that sodium fluoride be specifically named in the regulation.

The majority of submissions objecting to the proposed amendment provided a response to Question 2. These responses essentially restated the case that fluoride was added to water as a treatment for dental caries, not as a water treatment, and as such was a medicine. These claims have been considered and responded to in Question 1 above.

Outcome

None of the objections to the proposal are specifically directed at responding to the question posed, and all of the objections have been previously considered in the analysis of the response to Question 1. No change to the proposed regulation is considered necessary.

The Ministry supports the suggestion from submitters supporting the proposed regulation that the exemption should include chemicals known to be, or likely to be, used for fluoridation of community water supplies. It is proposed that the wording of the regulation be amended to include sodium fluoride, hydrofluorosilicic acid (HFA), sodium silicofluoride (SSF) and other substances in routine use to fluoridate community drinking water.

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