

# PUBLIC BOARD PAPER HA09/019 MEETING – 26 FEBRUARY 2009

## Background to water fluoridation consultation

<b>2008/9 Annual Plan key area of responsibility to which the paper relates (please mark in bold):</b>				
<b>Health and Well-Being / Inequalities</b>	Improve Clinical Standards	System Reform	Workforce and Capability	SHA Leadership
Finance	Information Technology-Enabled Transformation	Knowledge Management	Governance	Performance
<b>Links to SCSHA Risk Register / Board Assurance Framework (please complete):</b>				
Risk Register Reference	4.2			
Risk Description	Failure to conduct an open and transparent water fluoridation consultation process to enable the Strategic Health Authority (SHA) Board to make an informed decision.			

### **Legal Implications (if any)**

- The public consultation into proposals to add fluoride to the water supply in parts of Southampton and south west Hampshire has been carried out in line with the requirements of the Water Act 2003.
- The original consultation plan and document was reviewed prior to consultation by SHA solicitors who confirmed that the process, plan and document are compliant with the Water Fluoridation (Consultation) (England) Regulations 2005.
- The consultation has been carried out in accordance with guidance issued by the Chief Dental Officer for England in February 2008 (attached at Appendix 1) and the Cabinet Office code of practice on written consultation (attached at Appendix 2).

### **Equality and Diversity Implications (if any)**

- The consultation plan and document were assessed prior to consultation against Equality Impact Assessment processes.

<p><b>Links to partnership working / public engagement (if any)</b></p> <ul style="list-style-type: none"> <li>• This paper outlines the background to the first public consultation on fluoridation to be carried out in line with the Water Act 2003. The consultation is the largest undertaken so far by South Central Strategic Health Authority.</li> </ul>
<p><b>Key Issues and Points for Discussion:</b></p> <ul style="list-style-type: none"> <li>• The consultation has been carried out in accordance with the Water Industry Act 1991 and the Water Act 2003.</li> </ul>
<p><b>Actions requested from / recommendations to the SHA Board:</b> The SCSHA Board is asked to note this paper.</p>
<p><b>Author(s) of paper:</b> Olga Senior, Director of Communications and Corporate Affairs</p>
<p><b>Responsible Lead Director(s) who has signed off this paper:</b> Olga Senior, Director of Communications and Corporate Affairs</p>
<p><b>Presenter(s) of paper:</b> Olga Senior, Director of Communications and Corporate Affairs</p>
<p><b>Other committees / groups where this paper / item has been considered:</b> None.</p>
<p><b>Date of paper:</b> 18 February 2009</p>

## **1. Introduction**

The public consultation into proposals to add fluoride to the water supply in parts of Southampton and south west Hampshire is the first to be carried out in line with the Water Act 2003.

The requirement for the Strategic Health Authority (SHA) to consider undertaking a public consultation follows a request made by Southampton City Primary Care Trust (SCPCT) to a predecessor SHA to carry out a feasibility study to determine whether there was a technically feasible and affordable scheme to fluoridate water supplies in Southampton and parts of south west Hampshire.

It was agreed at the SHA Board meeting held on 29 May 2008 that the above conditions had been met and that, in line with the appropriate legislation, the SHA should proceed with a public consultation on this issue.

## **2. Legislative background**

The relevant law concerning water fluoridation is the Water Industry Act 1991 and the Water Act 2003. The Act gives Strategic Health Authorities the responsibility of deciding whether adjusting the level of fluoride in the water supply is a feasible and affordable way to improve the dental health of the local population and to consult with the local population about any proposals to adjust the level of fluoride in the local water supplies.

The 2003 Act supersedes the 1991 Act (Section 87) to impose an obligation on water companies to adjust the level of fluoride in the local water supply if requested by a Strategic Health Authority.

The SHA carried out the consultation in line with the Water Fluoridation (Consultation) (England) Regulations 2005 and guidance issued by the Chief Dental Officer for England in February 2008. The SHA also carried out the consultation in line with the Cabinet Office code of practice on written consultation.

## **3. Grounds for undertaking a consultation**

3.1. The respective roles of Primary Care Trusts (PCTs) and Strategic Health Authorities (SHAs) in relation to water fluoridation proposals are clearly set out in a letter from the Chief Dental Officer sent to SHAs in February 2008 (Appendix 1, paragraphs 10-20 in the letter). It is for PCTs to assess the health needs of their populations and, where they think it is justified, to ask SHAs to investigate the feasibility and cost of water fluoridation.

3.2. The SHA should therefore proceed to a consultation if:

- it has been requested to do so by a local PCT
- a technically feasible scheme has been identified
- the cost of the scheme seems affordable

These issues were discussed by the SHA Board at its meeting on 29 May 2008 (Board paper HA08/046). Following those discussions, the SHA Board agreed unanimously to authorise public consultation on the proposed scheme to adjust levels of fluoride in the water supply to the Greater Southampton area.

- 3.3. If a feasible scheme is identified, it is the SHA's responsibility to undertake a consultation to assess the level of local support for the scheme. In light of the decision made at the Board meeting in May 2008, a comprehensive consultation process was developed and presented to the SHA Board at its meeting on 26 July 2008 (Board paper HA08/065).

Following the consultation, the SHA should consider the representations it receives and decide whether or not the health arguments in favour of the scheme outweigh all arguments against proceeding with the scheme.

## 4. Legal and ethical issues

### 4.1. Human Rights

It was suggested at the May 2008 SHA Board meeting that the fluoridation of the water supply may infringe the human rights of people within the proposed area in Southampton, and in particular that it may breach Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms. This article provides that "*Everyone has the right to respect for his private and family life, his home and his correspondence*" and that "*There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.*"

The European Commission of Human Rights considered whether fluoridation of drinking water in order to prevent dental caries was compulsory medical treatment in the case of *Jehl Doberer v Switzerland [European Commission of Human Rights (First Chamber) (1993), Application No. 17667/91 by Guy Jehl-Doberer against Switzerland]*. In this case, the complainant argued that fluoridation violated his right to privacy, under Article 8 of the European Convention. This is the convention that was adopted in UK law by way of the Human Rights Act 1998. The European Court of Justice (ECJ) ruled that Article 8 rights are relative rights, not absolute, and that therefore other considerations, such as the benefits to public health, countered any right that the complainant may have not to have his water supply supplemented with fluoride.

Some campaigners argue that fluoridation is also a breach of Article 3 of the Convention. This is an absolute right, from which there can be no 'derogation' (exemption), and states that "*No one shall be subjected to torture or to inhuman or degrading treatment or punishment*". This article will cover compulsory medication, but the threshold at which an Article 3 violation is triggered has been set very high by the Courts. There has

been no finding by the ECJ that the fluoridation of the water supply breaches Article 3.

It has also been suggested that fluoridation of the water supply may be in breach of the Convention on Human Rights and Bio Medicine or the Charter of Fundamental Rights, but these are not actionable under UK law. The Convention on Human Rights and Bio Medicine has not been signed by the UK, and the Charter of Fundamental Rights does not have legal effect.

In summary, the SHA is not aware of any UK or European case law that has determined that fluoridation of water is in breach of the European Convention on Human Rights.

#### 4.2. Mass medication

The Medicines (Advertising) Regulations 1994 prohibit the advertisement of "*relevant medicinal products*" in respect of which no marketing authorisation is in force. This prohibition only applies where a product is a medicinal product for human use to which Directive 2001/83/EC applies. The definition of medicinal product is "*any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.*"

The current position in the UK in respect of fluoridation is that it is not medication and that it is not a means of curing a disease. The UK Medicines and Healthcare Products Regulatory Agency (MHRA), which licenses medicinal products in the UK, has indicated that fluoridation of water is not within its remit. Fluoridation of water at the water treatment stage also does not fall within the remit of the Food Standards Agency as a fortified food, because it is not legally considered to be such a food. On this basis, these provisions do not apply.

As indicated in section 4.1 above, the European Commission in the Jehl-Doberer decision concluded that adding fluoride to drinking water did not amount to compulsory medical treatment. In addition, the Scottish case of *Mrs Catherine McColl v Strathclyde Regional Council* [*Opinion of Lord Jauncey in causa Mrs Catherine McColl (A.P) against Strathclyde Regional Council, The Court of Session, Edinburgh, 1983*] considered whether fluoridating the water supply came within the Medicines Act 1968 and held that it did not.

It has been suggested that individual consent is required for any type of medical treatment, and that to medicate without consent constitutes assault. As it is not accepted that fluoridation is medication, consent is not required. Drinking water is treated with other products prior to consumption, such as chlorine, and consent is not sought for these.

#### 4.3. Safety

The case as to whether fluoridation is a safe and effective measure was discussed in Parliament and subsequently debated and enacted in the Water Act 2003 which enables local PCTs to request SHAs to carry out a public consultation on the issue. The SHA is confident that MPs, in a free vote, would not pass legislation allowing any public health measure which has the potential to harm health. The World Health Organisation (WHO) also endorses water fluoridation as *"the most effective public health measure for the prevention of dental decay."* (WHO, 2001)

#### 4.4. Ethics

The Nuffield Council on Bioethics report "Public health: ethical issues" (2007) argues that decisions about fluoridation should be taken within a democratic framework. However, in line with the Water Act 2003, the Government has prescribed that those decisions are taken by SHAs following consultation with the public.

Ethics committees were introduced in 1991 to advise on the extent to which proposals for research studies comply with recognised ethical standards. As over 5 million people in England receive fluoridated drinking water, with some schemes dating back to the 1960s, a new fluoridation scheme is not considered to be a research study. The evaluation of the original research studies upon which the fluoridation programme was based is the subject of the report 'The Conduct of the Fluoridation Studies in the United Kingdom and the Results Achieved after Five Years,' Her Majesty's Stationery Office, 1962.

### **5. Requirement for the Board to assess the cogency of arguments**

The Water Fluoridation (Consultation) (England) Regulations 2005 state that *"A Strategic Health Authority shall not proceed with any step regarding fluoridation arrangements that falls within section 89(2) of the Act unless, having regard to the extent of support for the proposal and the cogency of the arguments advanced, the Authority are satisfied that the health arguments in favour of proceeding with the proposal outweigh all arguments against proceeding."*

"Cogency" is not defined in the relevant legislation, but is defined by the Oxford English Dictionary as relating to a "clear, logical, and convincing" argument.

The Chief Dental Officer for England issued guidance in February 2008 that SHAs considering proposals to fluoridate the water supply should consider whether responses to the consultation are

*"evidence based and if so:*

- *the quality of the evidence presented*
- *the relevance of the representations to the health arguments in relation to fluoridation*
- *the nature of the individual / body making the representations in terms of who they represent and the way in which they gained their own members' input into the response."*

However, this does not mean that responses that are not evidence based should be disregarded. They are relevant in assessing the extent of support for the proposals, but will not attract as much weight in the decision-making process as those responses that are evidence-based and more cogent.

## **6. Responsibilities of SHA staff**

Although individual members of SHA staff may, from a personal or professional point of view, support water fluoridation, the SHA has a corporate responsibility to carry out an objective assessment of the consultation responses. The SHA has remained objective throughout this process and commissioned independent expert support in undertaking an objective analysis of responses.

## **7. Conclusion**

The SCSHA Board is asked to note the background to the consultation.

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18 February 2009