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OPEN LETTER

Dr Geoffrey Harris,
Chairman, South Central Strategic Health Authority
16th February 2009

Dear Dr Harris,

Appeals from your recent eminent correspondents that you should take due cognisance of professional medical concerns over fluoridation are entirely to be applauded. But the primary consideration in respect of fluoridation is not whether it is feasible, or even safe and effective. The definitive criterion that must first be met is that the practice is legally permissible.

I am writing to you to inform you that water fluoridation is in breach of both European Community and English law, and that any decision to endorse the fluoridation of Southampton's water supply is open to challenge at all levels in both the UK and in European Courts. The legal analysis that you published in your ***Fluoridation Consultation Document*** was grossly incompetent and misleading, and provided an invalid review on which any form of consultation, at any level, can be founded.

The practice of water fluoridation that your SHA is about to consider implementing is in violation of legislation passed by the European Community in respect of the licensing and use of medicinal products. It is also incompatible with the Directives on Water Quality and on Waste. Any recommendation on your part that it should be imposed in Southampton would be both improper and unethical. In addition, in the absence of the mandatory medicinal Product Licence, the promotion of the alleged medicinal properties of these nominated fluoridation chemicals, or of fluoridated water, is itself an offence, whether the product be regarded as a medicine or any form of foodstuff.

Authority of my statement

You will naturally wish to know on what authority I make these statements. For many years I have practiced as a Consulting Environmental Analyst, working as a Mission Leader for International Agencies on the assessment of projects in which compliance with a wide range of legislative frameworks has been an absolute requirement. Public health issues are an integral part of such analyses, so my comments below are based on some degree of practical familiarity with the application of legislation on public health.

Requirement of the SHA to exercise 'Due Dilligence'

Your correspondants have repeatedly emphasised their expert opinions that the practice of fluoridation is neither effective nor safe. This advice should be taken very seriously. However, I am fully aware that, as a subordinate unit of the Department of Health, the SHA is obliged to comply with official Government policy on this issue, regardless of public opposition. You should therefore be aware that both Board Members and Professional Staff of the SHA are likely to become personally accountable for the medical damages that will inevitably occur as a result of the implementation of this practice in Southampton.

Once any Public Servant is aware that issues of safety and legitimacy arise from a planned intervention, they are required to apply 'Due Diligence' to ensure that this information is brought to the attention of the relevant decision-makers within their organisation. Failure to do so may constitute a criminal offence. As a current example, the deliberate refusal of some members of the dental sector to record the prevalence of any form of fluorosis in England is an issue that may be held by a Court to constitute serious medical fraud, and demands immediate investigation.

You have been made aware by other professional correspondants that there are serious medical risks to the public with respect to the safety and the legitimacy of the practice. I am now informing you of the legal obstacles that also apply. Consequently, your Board Members and Officers would be prudent to seek immediate expert advice from both your own legal specialists and from their personal Professional Indemnity Insurance providers.

There is another issue, that has apparently been neglected by your SHA in its attempts to organise the 'Consultation' process that has attracted concern locally. Consultation requires that all Stakeholders should be informed of the key issues, and not merely those selected members of the general public whom you judge to be competent to provide 'cogent argument' on the issues raised by this practice. I suggest that before you attempt to reach a conclusion on fluoridation you inform all professional and managerial personnel within the SHA, your legal advisers, and the relevant Unions, that there are both medical and legal issues raised that might have direct and potentially highly unfavourable implications for them personally.

Failure of compliance of water fluoridation legislation in English law.

The nomination in the English legislation of the use of fluorosilicic acid (and its sodium salt) for water fluoridation inevitably invokes additional provisions and restrictions under the EC Directives on medicines, drinking water, and waste disposal. These constraints are all present in the English laws derived from the Directives. If you are under the impression that the fluoridation provisions of the 2003 Water Act supercede the mandatory requirement for the grant of a Marketing Authorisation (Product Licence) under the 1968 Medicines Act, you have been seriously misinformed. The practice that your SHA is about to consider is, by default, in violation of both EC and English law on medicinal products, despite the authorisation of the application of fluoridation chemicals by the water and fluoridation legislation.

Dilution does not constitute 'manufacture', so it is the source substances themselves for which a medicinal Marketing Authorisation is required. The industrial manufacture of fluorosilicates for this purpose under BS-EN 12174 and 12175 neither implies or authorises exemption from the requirement to hold the mandatory pharmaceutical Product Licences for their medicinal use.

The chief Executive Officer of the MHRA, Prof Kent Woods, has confirmed that no Application for the grant of a Product Licence has ever been made, either by the presumed nominal Licencee, the Secretary of State for Health, or any other legal entity involved in the practice. As the matter stands at present, no medicinal authorisation for the use of these chemicals is in force, and the practice is therefore in clear breach of the Medicines Act.

Exemptions for the use of unlicensed medicines

The use of unlicensed medicinal products is regulated by law. The MHRA has stated that

“Article 5 (1) of Directive 2001/83 establishes that Member States may put in place national arrangements permitting an authorised healthcare professional to commission the manufacture of an unlicensed medicinal product to meet the special needs of an individual patient under his direct personal responsibility.”¹ (emphasis added)

Fluorosilicic acid is delivered indiscriminately to the public through the public water supply, and clearly cannot comply with this regulation.

The English legislation dealing with the use of unlicensed products has been updated frequently, and guidelines have been issued by the MHRA, most recently on 7th February 2009.² These products or substances may only be supplied under the direct personal care of authorised health professionals. No exemption is granted for the use of fluorosilicic acid, and its medicinal use is prohibited.

1 <http://www.mhra.gov.uk/Howweregulate/Medicines/Reviewofunlicensedmedicines/index.htm> accessed 15Feb2009

2 <http://www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedallicence/Medicineshatdonotneedallicence/index.htm> accessed 15th February 2009

Fluoridation is 'medication', and subject to licensing

You may be under the misapprehension that the statement by the MHRA that the practice of fluoridation is not a medicinal intervention is definitive – if so, then you would again be in error. It is true that the Agency has in the past rejected demands that it be subject to regulation. It based this opinion on the statement that

*“it is for individual Member States to apply the definitions of medicinal products set out in Article 1 of the Medicines Directive (2004/27/EC) in respect of products within their borders”.*³

However, the Agency has misinterpreted the Directive in claiming that the product is not medicinal, and therefore that no Product Licence is required. The Directive does not give national authorities permission to ignore entirely, or exempt from regulation, any product that is used for the purpose of preventing or treating disease, or that is presented to the public as having medicinal properties. A number of European Court of Justice rulings⁴ establish unambiguously that :

‘if a product is represented to the public so that any averagely well-informed person gains the impression that the substance might have a beneficial effect on some medical condition, then that substance is a medicine under the terms of this Directive’.

The MHRA's position is therefore indefensible; it has no authority to refuse to regulate this product. Its repeated evasion of its statutory obligation to implement the Medicines Act is a matter that requires immediate attention by Parliament.

Prohibition on advertising the 'medical efficacy' of fluoridation..

As Earl Baldwin has confirmed, your SHA has engaged in a programme of propaganda. It unashamedly promotes the alleged 'benefits' of fluoridation to public and health professionals alike. So you should be aware that, since fluorosilicic acid has no relevant medicinal Product Licence, the promotion of its alleged efficacy and safety is prohibited under the Medicines Act and the Medicines (Advertising) Regulations. But you should also be aware that a similar prohibition this applies should you continue to maintain that the product is either a foodstuff or drinking water.

Attempting to persuade the public that it has such properties is an offence under both the medicines and the foods legislation, and severe personal penalties apply. The *Fluoridation Consultation Document* that your SHA issued publicly some months ago contains a number of such prohibited claims, and I have referred it to the NHS Counter Fraud Division for assessment, together with Earl Baldwin's criticism.

In conclusion

The issues raised here are of national significance, not least to those water undertakers presently fluoridating their product voluntarily. You will appreciate that I have not here referred to the issue of whether the State has the authority to order a private water company to carry out an action that is in breach of law. You may like to consider as a matter of urgency whether the SHA is prepared to attempt to procure an action that could precipitate legal proceedings to resist it, up to the level of the European Court of Justice itself.

Yours faithfully

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³ MHRA (2003) 'A guide to what is a medicinal product.' MHRA Guidance Note No. 8 (previously MAL 8) April 2003

⁴ Case C227-82 30 November 1983 re van Bennekom, European Court Reports 1983;3883.
Case C368-88 21 March 1991 re Delattre, European Court Reports 1991;I:1487.
Case C-60/89, 21 March 1991, re Monteil and Samanni, European Court Reports 1991;I:1547.
Case C219-91 28 October 1992 re Ter Voort, European Court Reports 1992;I:5485.