To: All interested organisations

25 June 2014

Our reference: DLC 1

CONSULTATION ON THE REVOCATION OF *'THE CLINICAL THERMOMETERS (EEC REQUIREMENTS) REGULATIONS 1993'*

Introduction

1. We are writing to consult you on the revocation of 'The Clinical Thermometers (EEC Requirements) Regulations 1993', hereafter referred to as "the Regulations".

Application to England, Wales, Scotland and Northern Island

2. This consultation is being made available in England, Wales, Scotland and Northern Ireland. The proposed changes would apply throughout the United Kingdom.

Proposal

3. MHRA proposes to revoke the Regulations by November 2014.

Background

4. The Regulations[1] came into force in October 1993 implementing the requirements of EEC Directive 76/764 (as amended by Directive 83/128/EEC and Directive 84/414/EEC) relating to clinical mercury-in-glass maximum reading thermometers.

5. Provisions within the Regulation include 'pattern approval and initial verification: the EEC signs and marks'. This provides that thermometers bearing such markings should be subject to free movement. However, such markings are now obsolete due to the CE marking requirements and associated EU free movement provisions of the Medical Devices Directive (93/42/EC). Furthermore, the Medical Devices Directive repealed Directive 76/764/EEC when it came into force and so the Regulation has no basis in European law.

6. The Regulation contains the power to issue a prohibition notice and powers of entry. Neither of these powers have been used by the Medicines and Healthcare products Regulatory Agency (MHRA) during the course of its enforcement activity as equivalent powers are available within the Consumer Protection Act (1987) and General Product Safety Regulations (2005) respectively.

7. The sale of mercury thermometers or sphygmomanometers to the general public has been prohibited since 3 April 2009. Furthermore, since 10 April 2014 Commission regulation (EU) no 847/2012 has prohibited the sale of mercury-containing sphygmomanometers, strain gauges for plethysmographs and thermometers to anyone, with an exemption for sphygmomanometers used in ongoing epidemiological studies

[1] http://www.legislation.gov.uk/uksi/1993/2360/made

and their use as reference standards in clinical validation studies of mercury-free sphygmomanometers.

Provision within the Regulation	Coverage in other legislation
Pattern approval and initial verification	CE marking requirements of 93/42/EC
Approval of bodies to consider pattern approval & initial verification	Does not reflect the current regulatory framework involving notified body activity in CE marking process
Power for SofS to issue a prohibition notice	Consumer Protection Act (1987) contains powers for SofS to issue a prohibition notice
Powers of inspection (powers of entry)	Equivalent powers in Consumer Protection Act (1987)

Impact assessment

8. We think that the proposals contained in this consultation document will have no substantive adverse impact on industry or on patients. Overall, we consider that the proposal has no new significant effect on the sector and will not impose any additional costs.

How to respond

9. We would be grateful if any comments in response to this letter could be emailed to: **devices.compliance@mhra.gsi.gov.uk**, alternatively they may be addressed to:

Ranulf Barman,
Compliance & Enforcement Unit,
Medical Devices,
Medicines and Healthcare products Regulatory Agency,
4th Floor,
151 Buckingham Palace Road,
London
SW1W 9SZ

Comments must arrive no later than **4 August 2014.** Comments received after this date will not be taken into account.

Circulation of proposals

10. This consultation letter is being brought to the attention of those organisations listed at Annex A. Copies of the consultation are also available from our website - **www.mhra.gov.uk** and replies are welcome from all interested parties.

11. This consultation abides by consultation criteria set out in the revised Code of Practice on Consultation published by the Department for Business Innovation & Skills and viewable in full via:

https://www.gov.uk/government/publications/consultation-principles-guidance

Responses: Confidentiality and Disclaimer

12. The information you send us may be passed to colleagues within the Government or related agencies. Furthermore, information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes. These are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004.

13. If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on us.

14. Please ensure that your response is marked clearly, if you wish your response (whole or in part) and name to be kept confidential. Confidential responses will be included in any statistical summary of numbers of comments received and summary of views expressed.

15. The Agency's Information Centre at 151 Buckingham Palace Road will supply copies on request. An administrative charge, to cover the cost of photocopying and postage, may be applied. Alternatively, personal callers can inspect replies at the Information Centre by prior appointment (telephone 0203080 6351).

APPENDIX 1

To: Ranulf Barman
Compliance & Enforcement Unit, Medical Devices Division,
Medicines and Healthcare products Regulatory Agency,
4th Floor,
151 Buckingham Palace Road, London SW1W 9SZ.

From: _____
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_____
_____

CONSULTATION ON THE REPEAL OF *'THE CLINICAL THERMOMETER (EEC REQUIREMENTS) REGULATION 1993'*

My comments on the proposals are below/ attached.

** My reply may be made freely available.*
** My reply is confidential.*
** My reply is partially confidential (indicate clearly in the text any confidential elements)*

Signed: _____
** Delete as appropriate*

APPENDIX 2

DLC1

NB: THE ATTENTION OF AT LEAST THE FOLLOWING HAS BEEN DRAWN TO THIS CONSULTATION. HOWEVER, THIS LIST IS NOT EXHAUSTIVE AND REPLIES ARE WELCOME FROM ALL INTERESTED PARTIES.

Association of British Healthcare Industries (ABHI)
British Healthcare Trades Association (BHTA)
British In Vitro Diagnostics Association (BIVDA)
RCN
BSI
PAGB
SGS (Inspection, verification, testing)
Sheffield University
NHS
NHS England
Academy of Medical Sciences
BAREMA
DH
NHS Confed
Wales
Northern Ireland
Scotland