# EXPLANATORY MEMORANDUM TO

# THE CLINICAL THERMOMETERS (EEC REQUIREMENTS) (REVOCATION) REGULATIONS 2015

## 2015 No. 419

**1.** This explanatory memorandum has been prepared by the Department of Health (DH) and is laid before Parliament by Command of Her Majesty.

## 2. Purpose of the instrument

2.1 This Regulation revokes the requirements placed on manufacturers of clinical thermometers using mercury within glass by the Clinical Thermometers (EEC Requirements) Regulations 1993. The original 1993 Regulations implemented Council Directive No.76/64/EEC, as amended, relating to mercury in glass thermometers. This Directive is no longer in force and these Regulations are therefore now obsolete.

## 3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

## 4. Legislative Context

4.1 The original Regulations which are to be revoked were made using section 2(2) ECA powers.

4.2 The subject matter of this Regulation may be regarded as concerning "Consumer Protection" and "Weights & Measures". The heading "Weights and Measures" reflects the subject heading of the original 1993 Regulations but "Consumer Protection" ensures that this Statutory Instrument is categorised with all the other Statutory Instruments that relate to medical devices.

The Secretary of State is able to make these Regulations for the whole of the United Kingdom.

## 5. Territorial Extent and Application

5.1 This instrument will apply across the United Kingdom.

## 6. European Convention on Human Rights

6.1 The Secretary of State for Health has made the following statement regarding Human Rights:

In my view the provisions of the Clinical Thermometers Revocation Regulations 2015 are compatible with the Convention Rights.

## 7. Policy background

7.1 The 1993 Regulations provide that it is an offence, subject to various exceptions:

- to trade in clinical thermometers that did not use the specified signs of EEC pattern approval, or the EEC pattern approval verification mark;
- to use the specified signs of EEC pattern approval verification mark on clinical thermometers where pattern approval authorisation had not been obtained;
- to manufacture in excess of the number specified, where EEC pattern approval was subject to a condition limiting the number of thermometers manufactured;
- to continue selling or using clinical thermometers when a Prohibition had been placed upon stock;
- to obstruct inspectors from inspecting clinical thermometers or remove authorisation marks where this was warranted.

7.2 These specific offences are not needed. Since 3 April 2009, placing mercury thermometers on the market for sale to the general public has been prohibited. On 10 April 2014, Commission Regulation 847/2012 extended this prohibition to include sale to professional users in the healthcare sector meaning that mercury thermometers can no longer be sold to anyone.

7.3 The revoking Regulations will come into force in April 2015.

## 8. Consultation outcome

8.1 On 25 June, the MHRA launched a six-week public consultation on draft Regulations to revoke the 1993 Regulations. The purpose of the consultation, which was sent directly to key Stakeholders[1], was to seek views on the draft Regulations before these were made. No responses were received from the consultation and there was no indication that the implementation of these proposals would cause any controversy.

8.2 Given that the 1993 Regulations relate to mercury-containing thermometers and that placing such products on the market is prohibited across the EU, little concern was anticipated. Furthermore, the original Directive upon which they were based was repealed more than 20 years ago.

## 9. Guidance

9.1 It is not anticipated that any extensive guidance will be necessary, given that the 1993 Regulations have not been used for some time and will no longer have effect. There will be publicity available on the MHRA website at https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency to inform enforcement officers who work with related products of this revocation before it comes into force in April 2015.

## 10. Impact

10.1 We have not identified any impact on business, charities or voluntary bodies.

[1] Key Stakeholders consulted include: Association of British Healthcare Industries (ABHI), British Healthcare Trade Association (BHTA), British In Vitro Diagnostics Association (BIVDA), British Standards Institute (BSI), NHS England and the Devolved Administrations

10.2 There appears to be little impact on the public sector. There does not appear to have been use of the Regulations for some time, either in issuing enforcement notices or prosecutions in the courts.

10.3 A link to the public consultation can be found below

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/323987/Consultation_-_Revocation_of_the__Clinical_Thermometer_Regulations_1993.pdf

## 11. Regulating small business

11.1 The legislation applies to all businesses but will have no impact given that mercury-in-glass thermometers are no longer manufactured.

## 12. Monitoring & review

12.1 There are no plans to re-introduce the production of mercury-in-glass thermometers; such products have been replaced by new digital technologies. However, we will include a formal requirement to review in the Regulations within 5 years.

## 13. Contact

Ranulf Barman at the Medicines and Healthcare Products Regulatory Agency, an Executive Agency of the Department of Health Tel: 0203 080 6000 or email: ranulf.barman@mhra.gsi.gov.uk can answer any queries regarding the instrument.