EXPLANATORY MEMORANDUM TO

THE MEDICAL DEVICES (AMENDMENT) REGULATIONS 2005

2005 No. 2909

1. This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health, and is laid before Parliament by Command of Her Majesty.

2. Description

2.1. These Regulations amend the provisions of the Medical Devices Regulations 2002 relating to enforcement. This amendment has been made in order to ensure that local authorities continue to have a duty to enforce the 2002 Regulations in relation to medical devices which are intended for consumers.

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

3.1. There are none.

4. Legislative Background

4.1. The Regulations are made under the powers conferred by section 2(2) of the European Communities Act 1972, and by section 27(2) of the Consumer Protection Act 1987, and amend regulation 61(3) of the Medical Devices Regulations 2002. The Medical Devices Regulations 2002 implement various European Community Directives on the safety of medical devices. Regulation 61(3) provides that local authorities (in practice, Trading Standards Officers) have a duty to enforce the Regulations in relation to medical devices which are consumer goods for the purposes of Part II of the Consumer Protection Act 1987. The Secretary of State for Health, has enforcement duties in relation to all medical devices. In practice, such powers are exercised by the MHRA. In relation to consumer goods, those duties were exercisable concurrently with local authorities.

4.2. Section 10 of Part II of the 1987 Act provided a definition of consumer goods. Section 10 has now been repealed by the General Product Safety Regulations 2005 ("the GPS Regulations") which came into force on 1 October 2005. The GPS Regulations transpose the General Product Safety Directive 2001/95/EC and incorporate a different definition of consumer products from that used in section 10 of the 1987 Act. As a result, there is now no definition of consumer goods for the purposes of regulation 61(3) of the 2002 Regulations and local authorities therefore have no duty to enforce.

4.3. The necessary consequential amendment was not included in the GPS Regulations. Once the omission had been identified, the Department prepared these Regulations as soon as reasonably practicable. Until these Regulations come into force, the Secretary of State will be solely responsible for enforcement in relation to medical devices which are consumer goods.

5. Extent

5.1. This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1. Not applicable.

7. Policy background

7.1. The policy intention is to ensure that Trading Standards Officers are responsible for enforcement in relation to the same category of products as before 1 October 2005. As the proposed amendment is purely consequential, a public consultation was not considered necessary.

7.2. The Local Authority Coordinators of Regulatory Services (LACORS) have been informed of the amendment and have been asked to cascade the information to their members.

8. Impact

8.1. A Regulatory Impact Assessment has not been prepared for this instrument as it has no impact on the costs of business.

9. Contact

9.1. The contact for further information on these Regulations is:

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