House of Lords
House of Commons
Joint Committee on Statutory Instruments

Sixth Report of Session 2012-13

Drawing special attention to:

Medical Devices (Amendment) Regulations 2012 **(S.I. 2012/1426)**

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Joint Committee on Statutory Instruments

Current membership

House of Lords
Lord Clinton-Davis *(Labour)*
Lord Geddes (*Conservative*)
Lord Kennedy *(Labour)*
Earl of Mar and Kellie (*Liberal Democrat*)
Lord Rees-Mogg *(Crossbench)*
Lord Selkirk *(Conservative)*
Baroness Stern (*Crossbench*)

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Toby Perkins MP (Labour*, Chesterfield*)

Powers

The full constitution and powers of the Committee are set out in House of Commons Standing Order No. 151 and House of Lords Standing Order No. 74, available on the Internet via www.parliament.uk/jcsi.

Remit

The Joint Committee on Statutory Instruments (JCSI) is appointed to consider statutory instruments made in exercise of powers granted by Act of Parliament. Instruments not laid before Parliament are included within the Committee's remit; but local instruments and instruments made by devolved administrations are not considered by JCSI unless they are required to be laid before Parliament.

The role of the JCSI, whose membership is drawn from both Houses of Parliament, is to assess the technical qualities of each instrument that falls within its remit and to decide whether to draw the special attention of each House to any instrument on one or more of the following grounds:

i. that it imposes, or sets the amount of, a charge on public revenue or that it requires payment for a licence, consent or service to be made to the Exchequer, a government department or a public or local authority, or sets the amount of the payment;
ii. that its parent legislation says that it cannot be challenged in the courts;
iii. that it appears to have retrospective effect without the express authority of the parent legislation;
iv. that there appears to have been unjustifiable delay in publishing it or laying it before Parliament;
v. that there appears to have been unjustifiable delay in sending a notification under the proviso to section 4(1) of the Statutory Instruments Act 1946, where the instrument has come into force before it has been laid;
vi. that there appears to be doubt about whether there is power to make it or that it appears to make an unusual or unexpected use of the power to make;
vii. that its form or meaning needs to be explained;
viii. that its drafting appears to be defective;
ix. any other ground which does not go to its merits or the policy behind it.

The Committee usually meets weekly when Parliament is sitting.

Publications

The reports of the Committee are published by The Stationery Office by Order of both Houses. All publications of the Committee are on the Internet at www.parliament.uk/jcsi.

Committee staff

The current staff of the Committee are Charlotte Littleboy (*Commons Clerk*), Jane White (*Lords Clerk*) and Liz Booth (*Committee Assistant*). Advisory Counsel: Peter Davis, Peter Brooksbank, Philip Davies and Daniel Greenberg (*Commons)*; Allan Roberts, Nicholas Beach and Peter Milledge *(Lords)*.

Contacts

All correspondence should be addressed to the Clerk of the Joint Committee on Statutory Instruments, 7 Millbank, London SW1P 3JA. The telephone number for general inquiries is: 020 7219 2026; the Committee's email address is: jcsi@parliament.uk.

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Instruments reported

At its meeting on 11 July 2012 the Committee scrutinised a number of Instruments in accordance with Standing Orders. It was agreed that the special attention of both Houses should be drawn to one of those considered. The Instrument and the grounds for reporting it are given below. The relevant Departmental memorandum is published as the appendix to this report.

1 S.I. 2012/1426: Reported for defective drafting

Medical Devices (Amendment) Regulations 2012 (S.I. 2012/1426)

1.1 **The Committee draws the special attention to these Regulations on the ground that they are defectively drafted in one respect.**

1.2 These Regulations amend the Medical Devices Regulations 2002. The only changes made to those Regulations are updating references to three European Directives and providing that references in the 2002 Regulations to the Annexes of those Directives are to be construed as references to those Annexes as amended from time to time.

1.3 Regulation 3(1) requires the Secretary of State from time to time to carry out a review of the provisions within these Regulations and publish a report containing the conclusions of the review. Regulation 3(2) requires the Secretary of State, in doing so, to have regard to how [two Directives] are implemented in other member States. Regulation 3(3)(a) requires the report to set out "the objectives intended to be achieved by the regulatory system established by the provision of these Regulations that implement the Directives mentioned in paragraph (2)".

1.4 The provision appeared to the Committee to be materially similar to one used in a previous case, in which the Committee considered a review provision relating to a single food additive, lycopene, that had been brought into the existing control system for food additives. In its 27th Report of Session 2010-12, the Committee had reported the Food Additives (England) (Amendment) (No.2) Regulations 2011 (S.I. 2011/1456) in the following terms:

> *These Regulations have effect to adjust the application to lycopene of the regulatory system established by S.I.2009/3238. Regulation 4 requires reviews; and paragraph (3) of that regulation requires the report of a review to set out and assess the objectives of "the regulatory system established by these Regulations". The Committee queried the terms of that paragraph in the light of the limited purpose of the Regulations. In a memorandum printed at Appendix 2, the Food Standards Agency states that the terms of paragraph (3) are closely based on the text of the Guidance on Sunsetting Regulations produced by the Better Regulation Executive and argues that those terms are not inappropriate, given that the Regulations establish an altered regulatory system for lycopene. The Committee considers that including in regulation 4(3) some specific reference to the regulatory system established by S.I.2009/3238 as, by virtue of the Regulations, it applies in relation to lycopene would have accurately indicated what a report of a review is*