



Transfer of responsibility for the Certificates of Free Sale for medical devices scheme to the Medicines and Healthcare products Regulatory Agency

The Department of Health has for many years issued certificates of free sale (CFS) to UK based medical device companies with the aim of supporting UK based industry and jobs by helping companies export their products to countries outside the European single market. For the reasons set out in this letter, the Department proposes to transfer responsibility for the administration of the scheme to the Medicines and Healthcare products Regulatory Agency (MHRA) with effect from 1 April 2014.

Because the proposed change has implications for the companies that use the scheme we are keen to get their reactions and those of the relevant trade associations to it. This letter initiates a consultation to which you are invited and to which we hope you will want to contribute.

Background

Medical devices sold or otherwise made available in the UK are regulated through EU directives implemented at national level by Member States, and display a CE mark to show that they comply with the requirements of the legislation. Importing authorities in some non-EU countries ask for letters from importers of medical devices confirming that the products in question are legally available on their home market. For UK-based companies, this means seeking confirmation from Government that devices are CE marked. That confirmation is supplied via CFS.

The certificates issued are non-statutory documents which state that a named medical device complies with relevant product legislation, as indicated by the CE mark, and therefore may be sold legally in the UK. Certificates do not state that products are actually on the UK market and in use, nor do they provide a guarantee of safety. They are issued in response to applications from UK based exporters, subject to the applicant meeting certain eligibility criteria and providing satisfactory written declarations about their product's regulatory compliance.

The interpretation and application of the devices regulations in the UK is primarily a matter for MHRA – the UK's competent authority. Given that the CFS scheme is concerned with providing an assurance that those regulations have been applied, it makes sense for the competent authority to have control of it. It is [no doubt] for that reason that other European countries give their competent authorities responsibility for the issue of CFS. The UK is, we believe, unique in not doing so.

The other characteristic of the CFS schemes run elsewhere in Europe not presently found here is that the cost of running the scheme is off-set by item of service fee income. If the

proposed change takes place, the MHRA would expect in due course (probably from 1 April 2015) similarly to charge manufacturers and their representatives a fee for processing CFS applications. The level of any such fee would be the subject of a separate consultation at a later point.

Consultation question

The CFS scheme is an adjunct to a regulatory regime that in the UK is the responsibility of the MHRA. The Department proposes therefore that the Agency should take on the operation of the scheme, and that the function should transfer from the Department of Health on 1 April 2014. Do you have views on the proposal or on the supporting rationale?

Duration of consultation

The consultation period begins on 20 November 2013 and runs until 10 January 2014

How can you respond to this consultation?

Please send your response, by e-mail, to:

CFSConsultation@dh.gsi.gov.uk

Please ensure your response reaches us by 10 January 2014.

When responding, please state whether you are doing so as an individual or are representing the views of a company or other organisation. If you are responding on behalf of a member organisation, please make it clear who the organisation represents and, where applicable, how the views of members were assembled. We will acknowledge receipt of your response.

We have sent this to the relevant trade bodies and to the individual companies who make regular use of the CFS scheme. Please do share this document with, or tell us about, anyone else you think will want to be involved in the consultation.

Any queries about the subject matter of this consultation should be made to

CFSConsultation@dh.gsi.gov.uk

Freedom of information

Following the end of consultations we shall publish a summary of responses received. Information people provide in response to our consultations, including personal information, may be disclosed in accordance with the Freedom of Information Act 2000 and the Data Protection Act 1998. If you want the information that you provide to be treated as confidential please tell us, but be aware that we cannot guarantee confidentiality.

For more information about the Freedom of Information Act please visit the Information Commissioner's website at: http://www.ico.org.uk/for_the_public/official_information.

Result of this consultation

You will be informed of the outcome of the consultation in due course.