September 2014

Our reference: MDL 2

Consultation on the proposal to introduce a fee for the Certificates of Free Sale (CFS).

Introduction

1. We are writing to consult you on the above proposal, where from 1 April 2015 the MHRA will be taking responsibility for CFS and are asking you for comments on the proposal to introduce a fee for each CFS application.

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 introduce a fee for the CFS from 1 April 2015.

Background

4. The Department of Health consulted with manufacturers on the proposal to transfer the CFS to MHRA in late 2013. The majority of responses were in favour of the transfer or had no specific issues on the handover, save for a continuation of the service and to ensure that the timescale of certification issue was maintained.

5. MHRA further agreed to consult with users again on the proposal to introduce a fee, to cover the costs of the service provided, in line with Government policy of self-funding.

6. This letter initiates a consultation to which you are invited and to which we hope you will want to contribute.

Additional Background [and rationale]

7. 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 a CFS.

8. 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.

9. 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 made sense for the competent authority to have control of it. It is for that reason that other European countries give their competent authorities responsibility for the issue of CFS.

10. The other characteristic of the CFS schemes run elsewhere in Europe and not presently found in the UK is that the cost of running the scheme is off-set by item of service fee income. MHRA would expect from 1 April 2015 similarly to charge manufacturers and their representatives a fee for processing CFS applications.

Impact assessment

11. We think that the proposals contained in this consultation document will have no substantive adverse impact on industry. Overall, we consider that the proposal has no significant effect on the sector and will impose only minor additional costs.

Questions

1. It has been agreed that the CFS scheme will be transferred to the MHRA and is expected to be live on 1st April 2015 at the latest. It has been agreed that as an adjunct to a regulatory regime that it is the responsibility of the MHRA. A fee will be charged at £75 per application. This is in line with other European certificate providers. This will ensure the service provided is efficient and effective.

Do you have views or comments on this proposal or on the supporting rationale?

2. In time we intend to move away from paper copies of the certificate if and where possible and to provide an electronic certificate for ease of transfer and to save on environmental costs.

Would this impact upon your business in any way? Are there any countries that you export to, where you know they would not accept an electronic copy?

3. As the MHRA is always looking to improve the service we provide, we would be looking at reviewing the current way CFS is provided.

Could you provide any suggestions that would improve the present service to your business that we may consider and would you be interested in joining a user's group to look at improving the CFS distribution and service to all users?

Are there any other comments or questions you would like us to take into account after this consultation which you would like to see implemented in April 2015, or at a later date?

Duration of consultation

4. The consultation period begins on 15 September 2014 and runs until 31 October 2014.

How to respond

5. We would be grateful if any comments in response to this letter could be emailed to: devices.compliance@mhra.gsi.gov.uk, and made 'for the attention of Mike Peel', alternatively they may be addressed to:

   Mike Peel
   Medical Devices,
   Medicines and Healthcare products Regulatory Agency,
   4th Floor,
   151 Buckingham Palace Road,
   London
   SW1W 9SZ

   Comments must arrive no later than 31 **October 2014.** Comments received after this date will not be taken into account.

Circulation of proposals

6. 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.

7. 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

8. 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.

9. 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.

10. 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.

11. 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).

Annex A

Association of British Healthcare Industries (ABHI)
British Healthcare Trades Association (BHTA)
British In Vitro Diagnostics Association (BIVDA)
RCN
BSI
PAGB
DH
NHS Confed
Wales
Northern Ireland
Scotland