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MEDICAL DEVICES (AMENDMENT) REGULATIONS 2013

1. I am writing to seek your views on the Medicines and Healthcare products Regulatory Agency (MHRA)'s approach to implementing Commission Regulations 722/2012 and 207/2012.

2. Commission Regulation 722/2012 replaces the existing requirements (contained in Directive 2003/32) placed on medical devices manufactured utilising non-viable tissues from Transmissible Spongiform Encephalopathies (TSE)-susceptible species. The affected animals are bovine, ovine and caprine species, deer, elk, mink and cats.

3. Commission Regulation 207/2012 enables manufacturers to supply instructions for use electronically for certain categories of general medical devices and active implantable medical devices should manufacturers so wish.

4. I would be grateful for responses to the questions asked in this letter by 7 May 2013. Please send responses by email to rebecca.brown@mhra.gsi.gov.uk.

Commission Regulation 722/2012

Context

5. Directive 2003/32 on medical devices put in place precautionary measures aimed at protecting public health and minimising the possibility of infection of humans with TSEs from the use of medical devices manufactured utilising animal tissues. The Directive was put into place following the emergence of variant Creutzfeldt-Jacob Disease (vCJD) in the UK in the mid-1990s and the increased profile of TSEs as a risk to human health.

6. Regulation 722/2012 repeats the existing provisions within Directive 2003/32 and updates them to reflect global experience. For example, manufacturers of devices utilising animal tissues from TSE-susceptible species must now take certain issues into account in their risk analysis and risk management.

7. The Regulation also extends the scope of the precautionary measures to cover active implantable medical devices (which are regulated under Directive 90/385). This is in addition to the general medical devices falling under Directive 93/42 which are already covered by the existing requirements.

Impact on UK business

8. The MHRA has estimated that fewer than 20 UK medical device manufacturers utilise animal tissues from TSE-susceptible animals. UK notified bodies assess on average eight medical devices utilising tissues from TSE-susceptible animals each year – most of which are manufactured outside of the UK.

9. There are two elements of Regulation 722/2012 that are likely to bring in additional costs for manufacturers:
   a) the extension of the Regulation to cover active implantable medical devices; and
   b) the new requirement for notified bodies to consult other competent authorities in the EU prior to approving an application for devices using European Directorate for the Quality of Medicines (EDQM) certified animal tissue.

10. Data gathered from UK notified bodies and the MHRA's own records show that the extension of the Regulation to cover active implantable medical devices will not bring in any additional costs. This is because, in practice, the rules in Directive 2003/32 are already being followed for active implantable medical devices.

11. The additional phase of consultation that notified bodies will have to undertake with competent authorities across the EU is likely to mean an additional cost impact of a maximum of £24,000 per annum for the relevant manufacturers.

12. We conclude that the impact of Regulation 722/2012 on UK business is negligible in the context of a general medical device sector with a turnover of £13bn in the UK.

Public health benefit

13. The Regulation benefits public health by improving the consistency of the legislation and bearing down on the small risk posed to the public from the use of these tissues in medical devices. The Regulation will further tighten controls and facilitate a uniformly rigorous approach to risk assessment, as well as provide additional confidence in minimising the possibility of infection of humans with TSEs from the use of such products.

Commission Regulation 207/2012

Context

14. Regulation 207/2012 sets out in which cases manufacturers may supply instructions for use (IFUs) in electronic format (e-IFUs) for general medical devices and active implantable medical devices.

15. The Regulation establishes the conditions under which manufacturers may produce these e-IFUs. This includes requirements on manufacturers to carry out a risk assessment of using e-IFUs, supply a paper copy of the IFU to a user if the user so requests, include certain information in the e-IFU, and keep the e-IFU available for a set period of time.

16. In addition, a notified body must verify the manufacturer's compliance with the relevant requirements before the device can be placed on the European market.

17. The Regulation aims to reduce costs on the medical devices industry and reduce the environmental burden, as well as potentially improve some aspects of safety by, for example, allowing swifter updating of IFU to address identified safety issues.

Impact on UK business

18. The MHRA surveyed the impact of this Regulation on UK industry before it agreed to support the measure. A survey with manufacturers was inconclusive in relation to the potential cost-savings anticipated. However given that e-IFUs are an optional measure, it was recognised that the regulation would not place an additional burden on manufacturers unless they identified a clear benefit themselves.

19. In general, comments from manufacturers suggest that they viewed the cost savings of e-IFUs as potentially significant. All respondents to our survey indicated that they would consider switching to e-IFUs.

20. The MHRA aims to undertake a further cost-benefit analysis, which we anticipate will demonstrate that the Regulation constitutes a simplification with a net benefit on industry. In the meantime, we welcome any information from stakeholders on cost savings as a result of switching to e-IFUs.

Amending UK legislation

21. In light of Commission Regulation 722/2012, we must amend the Medical Devices Regulations 2002 in two ways. Firstly, we will remove the provisions of the Medical Devices Regulations 2002 which implemented Directive 2003/32.

22. Secondly, we will make the directly applicable requirements of Regulation 722/2012 enforceable and effective in the UK. We will do this by amending the Medical Devices Regulations 2002 in order to:
    a) make manufacturers' compliance with Regulation 722/2012 (where applicable) a condition of affixing a CE mark, placing on the market, putting into service, and supply;
    b) make manufacturers' compliance with Regulation 722/2012 (where applicable) a condition of supply of custom-made devices and devices intended for clinical investigation;
    c) make notified bodies' compliance with Regulation 722/2012 (where applicable) a condition of notification;
    d) enable the UK competent authority to charge fees during inspections of notified bodies to ensure compliance with Regulation 722/2012; and
    e) ensure that the UK competent authority may enforce Regulation 722/2012 using Consumer Protection Act powers.

23. In light of Commission Regulation 207/2012, we will make its directly applicable requirements enforceable and effective in the UK. We will do this by amending the Medical Devices Regulations 2002 so that references to Annex I on the general essential requirements in the general medical devices directive or the active implantable medical devices directive also refer to Regulation 207/2012.

24. In addition, we will update the references in the Medical Devices Regulations 2002 to the European Economic Area (EEA), EEA States, Association Agreements, and Mutual Recognition Agreements to reflect changes over recent years.

25. We aim to have a draft statutory instrument available by the end of April. Please feel free to request this document if that would be helpful. Contact details are set out at the end of this letter.

Questions to stakeholders

Question 1: Do you have any comments on the proposed approach to amend UK legislation in light of Commission regulations 722/2012 and 207/2012?

Question 2: Do you agree with the MHRA on the impact on UK business of Commission regulations 722/2012 and 207/2012?

Question 3: Do you have information on devices that will be manufactured in the UK utilising animal tissues from TSE-susceptible animals in the future?

Next steps

26. Regulation 722/2012 will apply from 29 August 2013 except Article 4 which applied from 29 August 2012. Article 4 requires Member States to verify that the relevant notified bodies have up-to-date knowledge to assess the conformity of medical devices in line with the requirements of regulation 722/2012.

27. Regulation 207/2012 applied from 1 March 2013.

28. We will use responses to this letter to finalise our approach to amend UK legislation in line with Commission Regulations 722/2012 and 207/2012 by 29 August 2013.

29. I hope the information in this letter is clear. Many thanks in advance for taking the time to reply. Please do not hesitate to get touch if you have any questions.

Comments on the consultation process itself

30. If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

    Consultations Coordinator
    Department of Health
    3E48, Quarry House
    Leeds
    LS2 7UE
    e-mail: consultations.co-ordinator@dh.gsi.gov.uk

31. Please do not send consultation responses to this address.

Confidentiality of information

32. We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter.
    www.dh.gov.uk/en/FreedomOfInformation/DH_088010

33. Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Freedom of Information (Scotland) Act 2002, the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

34. 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 to us 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.

Yours faithfully,

Rebecca Brown
Medical Devices EU Policy Manager

Annex A: Checklist for Analysis

Proposal for a Regulation to replace Directive 2003/32/EC, concerning medical devices manufactured utilising tissues of animal origin
Date: 5 January 2012

What are the potential impacts of the Commission proposal on the UK?

Summary
The proposed Regulation is intended to replace existing requirements (contained in Directive 2003/32/EC) regarding medical devices manufactured utilising tissues originating from TSE-susceptible animals (these are bovine, ovine and caprine species, deer, elk, mink and cats). The draft text has been updated to reflect global developments and experience gained in the period since the adoption of Directive 2003/32/EC. The proposal will extend the scope to now cover active implantable medical devices regulated under Directive 90/385/EEC, in addition to the general medical devices falling under Directive 93/42/EEC which are already covered by existing requirements. These are primarily precautionary measures aimed at protecting public health and minimising the possibility of infection of humans with Transmissible Spongiform Encephalopathies (TSEs) from the use of such products.

The requirements detailed in the draft Regulation are to be complied with by manufacturers utilising animal tissues in addition to those specified within the main overarching Directives. The text sets out the aspects to be taken into account by manufacturers during their risk analysis and risk management in order to minimise the risk of transmitting animal spongiform encephalopathies to patients or other persons via medical devices. As these types of device fall within the highest risk category of the regulatory framework, compliance with the relevant requirements must be verified by a Notified Body before the product can be placed on the European market. The extension of scope and revisions reflected in the draft Regulation will further tighten controls and facilitates a uniformly rigorous approach across the EU.

Affected Groups
This proposal will affect medical device manufacturers that produce devices utilising animal tissues from TSE-susceptible species and Notified Bodies that are responsible for the pre-market assessment of medical devices. As it is a Regulation, it will affect all manufacturers marketing these products in the EU (irrespective of where they are based), and all Notified Bodies that have been designated to assess products under Directives 2003/32/EC, 90/385/EC and/or 93/42/EEC. It will also have a small impact on the UK Competent Authority – the Medicines and Healthcare products Regulatory Agency (MHRA).

The medical technology sector is a significant manufacturing sector in the UK, comprising over 3,000 companies with turnover of £13bn. The vast majority of these companies are small and medium sized enterprises (SMEs)[1].

Costs and Benefits
Despite the significant size of the UK medical technology market, only a tiny proportion of that market will be affected by the Regulation. This is because the number of medical devices that are captured by the Regulation, and the number of manufacturers that manufacture these devices, is very small. We do not have reliable information on the precise number of manufacturers affected, but it is likely to be fewer than 20.

Data gathered from UK Notified Bodies and the MHRA's own records show that, since the original Directive came into force in 2004, around 55 devices utilising tissues from TSE-susceptible

[1] Office for Life Sciences, Strength and Opportunity

species have been assessed by UK Notified Bodies – an average of 8 per year. Our understanding of the market is such that we expect that these devices are likely to have mainly come from US-based manufacturers, but some will also have come from manufacturers based in the UK – but that this will likely number fewer than 10.

There are two elements of the new Regulation that are likely to bring in additional costs for manufacturers:

a) the extension of the Regulation to cover active implantable medical devices; and
b) a new requirement for Notified Bodies to consult other EU Competent Authorities prior to approving an application for devices using European Directorate for the Quality of Medicines (EDQM) certified animal tissue.

Considering (a) the extension of the Regulation, data from the only UK Notified Body designated for conformity assessment of active implantable medical devices show that they have had six assessments for such devices containing tissue from TSE-susceptible species since 2004. They have indicated that, in practice, they have already been following the same process as specified under Directive 2003/32/EC and so this extension will not bring any additional costs.

All Notified Bodies have identified a potential additional cost relating to the new requirement (b) to consult other Competent Authorities. Different Notified Bodies have assessed the cost impact in different ways, but considering all of the responses, an additional cost of £3,000 per application is a reasonable upper estimate. This reflects the additional time – of c1.5 days – of preparing a summary report to share with other Competent Authorities and acting on any responses. This cost will be passed directly to a manufacturer by the Notified Body; for context, the additional cost would represent an additional 10% on a typical assessment which costs around £30,000 in total.

Our best estimate, therefore, based on the figures available is that this regulation will put a total additional cost on manufacturers of **£24,000 per year**. The cost on UK-based manufacturers is likely to be lower than this figure, reflecting the fact that devices incorporating such animal tissue placed on the UK market are mainly manufactured in the US. Given the paucity of data that we hold on this, however, it is appropriate to consider this figure as the potential maximum additional cost.

The benefits of the proposal are less tangible, since they are largely related to improving the consistency of the legislation and bearing down on the (already small) risk posed to the public from the use of these tissues in medical devices. However, it will further tighten controls and facilitate a uniformly rigorous approach to risk assessment, and provide additional confidence in minimising the possibility of infection of humans with TSEs from the use of such products.

Enforcement

Given the tiny impact that this proposal would have, we do not anticipate any additional impact on enforcement above and beyond that that is already in place in relation to the MHRA's responsibility for enforcement of the relevant medical devices directives.

Legal Implementation

As a Regulation, the proposal will be directly applicable to the UK.