October 2013

Medical Devices Briefing

Royal College of Surgeons

RCS ADVANCING SURGICAL STANDARDS

Briefing for the European Parliament ahead of the plenary session

Introduction

The Royal College of Surgeons (RCS) is a professional body with a remit covering England, Wales and Northern Ireland. Surgeons use medical devices when treating patients; public and professional confidence in device safety and performance is therefore of paramount importance.

Medical implants and devices more widely have brought significant benefits to patients, so it is important that the EU and its member states continue to encourage innovation. However, this should not happen at the expense of patient safety.

We broadly support the Directive in its current form and this briefing highlights particular aspects of the Directive (affecting medical devices) we would like to see supported by the EU Parliament.

Notified bodies

The RCS is extremely concerned that, at present, a device failing to meet the approval criteria of one notified body may gain approval from another, less stringent, notified body elsewhere. This is a serious risk to patient safety.

We are therefore pleased that the ENVI Committee has proposed compromise measures to address these concerns. In particular we welcome:

- The proposal for a category of special notified bodies to assess class III devices;
- More stringent criteria for approving notified bodies;
- Requiring clinical, including surgical, expertise on the proposed Medical Device Co-Ordination Group.

We urge the European Parliament to support these proposals and other similar measures to improve standards across notified bodies.

Unique Device Identification (UDI) codes and implant cards

The RCS supports both UDI codes and the provision of an implant card for patients detailing key information about their medical devices. We are pleased that the ENVI Committee has amended Article 16 to ensure information on an implant card is also transposed into a patient's medical records. Cards are often mislaid so this will help to ensure the information remains accessible to clinicians and patients.

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We agree with the current wording of the Directive that the card should contain details of the devices' UDI codes, the manufacturer, any relevant warnings and information about the expected lifetime of the device.

UDI codes, in particular, are a crucial measure to ensure traceability of implants. Beginning the assignment of UDI codes with the highest risk devices may be a necessary measure, but lower class devices should not be arbitrarily excluded from this process. The current proposals should not be weakened.

To ensure complete traceability and transparency, implanted 'in-house' medical devices should also contain UDI codes.

Post-market surveillance

We agree that notified bodies must assess the post-market surveillance plans of manufacturers, using specialist clinical expertise. The results of this assessment should be a factor when considering device approval.

It is important that the role of surgeons and other healthcare professionals in reporting performance and safety concerns of a medical device is clear. Requiring healthcare professionals to report incidents is supported by the College. We therefore encourage member states to make clear what role they expect healthcare professionals to play in incident reporting when this Directive is implemented.

Cosmetic interventions

The College strongly supports the Commission's proposal to include 'implants for the modification or fixation of body parts' within the scope of the legislation.

We also agree with the amendment from the ENVI Committee (recital 12b) that states that the advertising of cosmetic surgery should be better regulated. The RCS believes advertising should be for the sole purpose of conveying factual information to patients. It should not convey information to unduly influence a patient's decision, or encourage unnecessary or excessive procedures.

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