September 2013

Medical Devices Briefing

Royal College of Surgeons

Amendments to the draft Medical Devices Regulations

Briefing for the lead committee: Environment, Public Health and Food Safety (ENVI)

The Royal College of Surgeons (RCS) is a professional body with a remit covering England, Wales and Northern Ireland. The College has a particular interest in medical device regulation as surgeons are core users of such devices in the treatment of patients, and therefore must have confidence in medical device safety and performance.

Medical implants and devices more widely have brought significant benefits to patients, and therefore continual innovation in this field must be encouraged and facilitated. This should not however happen at the expense of patient safety. In this briefing, we set out our position on the European Commission's proposal and committee amendments (the numbers of which are found in brackets) for the revised regulation covering **medical devices** ahead of the scheduled vote on 18 September 2013.

Committee members will be well aware of the impact of faulty PIP implants and the patient safety failure of metal-on-metal hip implants, this legislation is an important step forward for patient safety and the College would urge all those involved to keep to the timetable over the coming months.

Unique Device Identification (UDI) codes and implant cards

- (406,407,410, 412-416) The College strongly supports both UDI codes and the provision of an implant card for patients detailing key information about their medical devices. Cards however are often mislaid and the detail available on an implant card must also be kept in the patient's medical records, and available electronically to the patient at their request.
- (418, 420-424) The implant card should be provided following the procedure and not as a proxy for a surgical consent form. The card should contain details of the devices' UDI, the manufacturer, any relevant warnings and information about the expected lifetime of the device.
- (443-444) UDI codes are a crucial measure to ensure traceability of implants. Beginning the assignment of UDI codes with the highest risk devices may be a necessary

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measure, but lower class devices should not be arbitrarily excluded from this process. The current proposals should not be weakened.

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

Notified bodies

- (715, 811, 815) Notified bodies must have access to appropriate clinical expertise when they need it. It is extremely important that there is medical involvement in CE marking decisions.
- (520) If a national authority has suspended a notified body, annulling the suspension should only happen when the notified body has been deemed fit, not as a result of a lapsed period of time.

The Medical Device Coordination Group (MDCG) and European level assessment

- (261) 'Clinical evaluation' should assess safety, performance and the efficacy of a device. Having this assessment take place at European level - by appropriate experts - will ensure a consistent view of the efficacy of a device across member states, which is welcome.
- (496-498) If the assessment team and responsible national authority cannot agree on an application, the MDCG should be made aware of the reasons for this. A notification decision which goes against the MDCG's recommendation should only be permissible on clearly stated, objective grounds.
- (502, 712-714) Increasing the level of scrutiny for notified bodies dealing with class III devices would help to raise their quality.

Post-market surveillance

- 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.
- (632) 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.
- (456) When manufacturers draw together a summary of the safety and clinical performance of a class III device, the inclusion of post-market evaluations is important.
- (633, 634, 641, 652, 653, 655-662, 664-666, 671) The learning from post-market surveillance is only valuable if incidents are reported. All information which can be used for learning purposes should be collated.

Cosmetic interventions

- (236) 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.

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