

The Webscout

Medical devices

Medical devices range from things as simple as an injection needle to implantable pacemakers and MRI imaging devices. A video by the WHO (<http://t1p.de/WHOVideo>) gives you an impression of the variety of medical devices and their importance for health; it reminds you as well of the unequal access to life-saving medical equipment. The WHO publishes a compendium of devices (<http://t1p.de/WHO-compendium>) that could be afforded in low-resource settings to offer solutions to health care issues, especially in developing countries. Such devices include an electrochlorinator designed to provide safe drinking water, but also mobile ECG devices. A film produced by Trinity College Dublin illustrates the role of medical devices in health care and the research efforts made to develop next-generation medical devices: <http://t1p.de/TrinityVideo>.

In the EU, medical devices are regulated by three directives that distinguish between active implantable medical devices, in-vitro diagnostic medical devices and all other medical devices. The regulatory framework can be found on the website of the European Commission (EC) (<http://t1p.de/Framework>).

It is not always easy to decide whether a product is a medical device or not. The decision generally falls to national authorities. However, to harmonise interpretations and protect the EU single market principle, the EC issues and updates a manual on so-called borderline products. The manual describes borderline classification cases, which serve as a decision tool for the member states. It can be found on the EC website: <http://t1p.de/EC-Borderline>. As the manual shows, the classification depends not only on the product itself, but also on the purpose it serves. The decision on shoe covers distributed in hospitals illustrates this point. Shoe covers “intended by their manufacturer to be used in operating rooms, intensive care units or immunodepressed patients to protect the patient from potential contamination are medical devices.” However, “shoe covers for visitors even in a hospital are products of control of environment”. Discussions on whether a tool is a medical device or not can appear rather odd. This is illustrated by a discussion on YouTube videos for treating insomnia: <http://t1p.de/Video-Insomnia>. The videos contain relaxing noises intended to help patients with insomnia to calm down and

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fall asleep. They do not differ much from videos for meditation, which would not be subject to a medical devices discussion. The insomnia videos, by contrast, would formally fulfil the criteria for medical devices due to the claim that they can be used to treat an illness. It might seem a little strange to classify a video as a medical device. However, with the increasing number of health applications on mobile devices, the classification of eHealth tools might become a regulatory issue.

Regulatory issues are not the only potential problems with medical devices. As they can be highly sophisticated, their use can be a costly burden for health care systems. Therefore, medical devices are subject to health technology assessment (HTA). To guide manufacturers and health policy decision makers, the WHO is working on a technical series on HTA for medical devices. A reference document at www.who.int/medical_devices/assessment/en/ gives an introduction to HTA.

The methods applied in HTA for pharmaceutical products are often inappropriate for medical devices. Drummond et al. summarise the additional challenges associated with assessments of medical devices. For example, the value of a diagnostic device is inextricably linked to the

benefit of a subsequent treatment and therefore hard to assess. Further, designing studies according to the principles of pharmacological interventions can be difficult. For example, sham procedures for a double-blind study design become unethical for surgical interventions when you have to assess the value of devices used in surgery. To learn more about the issues in HTA of medical devices you can download the full article here: <http://t1p.de/Drummond>.

So what can be done to overcome these issues? Tarricone et al. discuss the role of real-world evidence in medical device assessments in a review that is available at <http://t1p.de/Tarricone>. They describe the case of MitraClip, an implant for patients with moderate-to-severe mitral regurgitation. For this device, a sound randomised controlled trial (RCT) was not possible. The authors argue for the acceptance of real-world data, at least in cases where RCTs cannot be performed.

As you can see, medical devices are a complex topic. Regulations will continue to be updated to address unsolved classification and assessment issues. It is worthwhile to follow the changes, as medical devices are a great source of business for medical writers.

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