When is a medical device not a medical device?

Although the medical devices regulations have been in place for many years, there are areas where classification is unclear and confusing

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When is a medical device not a medical device? Medicinal products are regulated under the Medicines Act 1968, the Medicines for Human Use Regulations 1994 and amending regulations that transpose European legislation into UK law. Medical devices are regulated by three directives, the main one being the Medical Devices Directive 93/42/EEC. These directives have been transposed into UK law by Statutory Instrument 2002/618 and other amending regulations.

Because legislation on medicinal products predates the medical devices regulations, products have been reclassified, over time, in accordance with changes in EC legislation. Many products have transferred from being regulated under the medicines legislation to being regulated under the medical devices regulations.

The main group of products that were reclassified were dressings, some dental products, absorbable surgical material, non-hormonal intra-uterine devices, contact lens care products and irrigation solutions intended for mechanical rinsing. As the definition of a medical device was broadened by a further European directive, additional product groups were added to the list of medical devices. They included artificial tears, non-medicated dermatological products, zinc oxide products and aluminium salts, such as aluminium sulphate (astringents).

The revised definition of a medicine is any substance or combination of substances presented as having properties for treating or preventing disease in human beings, or any substance or combination of substances which may be administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic means, or to making a diagnosis.

The definition of a medical device, on the other hand, is any instrument, apparatus, appliance, material or other article, whether used alone or in combination, to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- Investigation, replacement or modification of the anatomy or of a physiological process;
- Control of conception;
- and which does not achieve its principal intended action by pharmacological, immunological or metabolic means but which may be assisted in its function by such means.

In the case of a medical device, the principal intended action is typically fulfilled by physical means although it may contain a medicinal substance that acts on the body in a manner ancillary to the device. If the medicinal substance acts in a manner that is more than ancillary, the product is regulated as a medicinal product. This is a grey area and here lies the problem.

“Have the regulations gone too far in reclassifying medicines as medical devices? Do we need to take a step back and redefine the criteria for reclassification?”

A heparin-coated catheter, for example, is considered to be a device incorporating, as an integral part, a substance, which, if used alone may be considered to be a medicinal product but in this case, the substance is liable to act on the body with action ancillary to that of the device. The Medicines and Healthcare products Regulatory Agency has offered an opinion that “integral” means a single component product rather than a pack containing two components (drug and device).

In an excellent review published in The Journal (26 June 2010, pp633–8), Lucy Titcomb poses the question “are quality standards being reduced as eye drops are classed as devices?”. She concludes by saying that “based on limited published data, pharmacists do not know whether the multidose, preserved artificial tear eye drops classed as devices meet the standards required for an in-use shelf life of four weeks let alone one in excess of that allocated to those classed as medicines”.

The issue becomes even more interesting when considering the TauroLock product range manufactured by TauroPharm GmbH. The TauroLock catheter lock solution, marketed in Germany as a medical device, is used to prevent catheter infection and occlusion. Three different presentations of TauroLock are available. They are TauroLock, a combination of 4 per cent citrate as an anticoagulant and cyclo-taurolidine as an antimicrobial, TauroLock with heparin for additional anticoagulation and TauroLock with urokinase for thrombolysis.

The urokinase in this pack is the same strength as the urokinase injection licensed for systemic use and marketed by a different company. There is a possibility that the urokinase component of the TauroLock device could be used as a stand-alone medicine. Given that urokinase is a biological thrombolytic extracted from male urine, safety is of paramount importance. Were it to be used as a stand-alone medicine, either accidentally or intentionally, the prescriber could not be sure that the product had met the same stringent safety requirements as the licensed version.

Looking into the future, it is not beyond the realms of possibility to imagine impregnating an anti-emetic medicine on to an intravenous administration set used to give chemotherapy to a patient. The main purpose of the set would be to administer the chemotherapy but the powerful anti-emetic would be released slowly to alleviate the patient’s symptoms. Would this then be classified as a medical device?

Have the regulations gone too far in reclassifying medicines as medical devices? Do we need to take a step back and redefine the criteria for reclassification?

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