How we regulate nanotechnology

Nanotechnology is enabling the creation of a whole range of materials which have novel properties. It is likely to have a wide impact on medical devices, leading to innovative devices. At the nanoscale, changes to the structure of a material can lead to changes in chemical or physical behaviour (i.e. nanoparticles behave differently from bulk materials). This presents the potential for the development of novel therapies, including smaller implantable devices.

A government commissioned report 'Nanoscience and nanotechnologies: opportunities and uncertainties' (external link), published in June 2004 by the Royal Society (www.royalsoc.ac.uk) and Royal Academy of Engineering (www.raeng.org.uk), has made a number of recommendations to government. These include that the Department of Health "review its regulations for new medical devices and medicines to ensure that particle size and chemistry are taken into account in investigating possible adverse side effects of medicines".

The government's response (external link) to this report was published on 25 February 2005, and progress reports have also been published since (see OST on nanotechnology (external link)). The Medicines and Healthcare products Regulatory Agency contributed to this response. The MHRA has since developed several activities related to assessing the risks and potential MHRA action steps for nanotechnology containing healthcare products. This has included organising a scientific conference and publishing a review of safety data. For more information, please see section under Safety information.

At the moment there are no regulations specific to medicines or medical devices using nanotechnology. The suitability of existing regulations is continually assessed as the area evolves.

For medicines, the Commission on Human Medicines has in September 2006 reviewed the toxicology of healthcare nanoparticles (for more information, please see section under Safety information). The European Medicines Agency (EMEA) published a reflection paper (external link) in June 2006 discussing the current thinking and the initiatives taken by the EMEA in view of recent developments in relation to nanotechnology-based medicinal products. Neither of these reviews identified an immediate need for nanotechnology specific regulation. It is likely that nanotechnology specific guidance will be created in the future, once there is enough data to allow for the creation of systematic guidance.

For medical devices, a European Medical Devices Expert Working Group has been set up on new and emerging technologies. This group is assessing the adequacy of the medical devices regulatory framework based on information presented by a specific nanotechnology task force. The existing regulations for medical devices require manufacturers to carry out an analysis of the risks associated with a medical device, to eliminate or reduce these where feasible, and to assess the balance of risks and benefits. Although the regulations for medical devices do not differentiate between medical devices that use nanotechnologies and those that do not, the MHRA is of the view that the existing regulations for medical devices and medicines are sufficiently broad in scope to cover risks associated with nanotechnology.

For medical devices, it is normal for particular requirements underpinning the Directives to be specified by European standards or European Commission guidance. European standards are being developed on nomenclature for nanoparticles and, within the wider context of biological safety, on physicochemical characterisation.

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