

## **P6 – Regulatory framework for nanotechnology in medical devices**

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### **ABSTRACT**

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In the health sector the development of products obtained by nanotechnology strategies offers innovative therapeutic and diagnostic opportunities. Nanomaterials (NMs) play an important role in the development of new therapies through new drug delivery systems, new products for diagnosis and imaging, vaccine development, etc. Include products that are regulated as medicines and others as medical devices (MDs). Along with the potential benefits of its use, safety issues have been raised, as well as regulatory challenges. Given that nanoproducts and their nanosimilars have complex manufacturing processes and molecular structures, the question is increasingly raised as to whether the current European Union (EU) regulatory framework for MDs is robust enough to authorize them. Currently there is a lack of a defined or even harmonized regulatory structure for approval of nanosimilars, which causes constraints in their approval. This whole scenario served as the basis for this review: give topics for discussion to create a future guiding document which allows to compare a nanosimilar with an innovative product maintaining quality, safety, and performance for the same medical procedure.

Key words: nanotechnology, regulation, medical devices, nanosimilars.