Regulatory issues in nanomedecine: a future under construction

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Research in nanotechnology and specially nanomaterials has gone now to a large commercial undertaking. The scientific literature on environment, health and safety aspects of nanomaterials show clearly how these aspects are now of primary importance. First of all the first question is: how to define nanomaterials and nanomedecine? Several definitions can be found but some initiatives tend to clarify these definitions. The application of nanotechnology to healthcare is already demonstrated by the increasing intensity of research and competition in the pharmaceutical industry. It can be illustrated by the design of new therapeutics and/or diagnostic tools. The field of new drug delivery technologies is also growing rapidly. The research on life sciences applications of nanotechnologies (mainly dedicated to drug delivery and therapeutics) has doubled since 2002. Nanotechnology-based drug delivery systems and devices provide new features and functions that other technologies cannot match. Various nanoscale structures of different size, shapes, texture and chemical compositions has been included as nanopharmaceuticals. Although there are quite a few approved nanopharmaceuticals, several others are under development or close to commercialization. There are currently several challenges and risks concerning the commercialization of nanopharmaceuticals. The most important are environmental, safety, ethical and regulatory issues. These products (drug-loaded nanomaterials or devices) displaying new size-dependent properties and toxicological profiles need new approaches from the regulatory agencies. A global approach is needed. Discussions concern the application of existing regulation and the implementation of new legislation in this field.

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