The European Regulatory Framework for Nanomedicines: Is It Suitable for the Future?

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The regulation of development, production and marketing of medicinal products is founded on the assurance of patients' health, stating requirements that manufacturers and Marketing Authorization holders must follow to guarantee quality, safety and efficacy. When the drug is based on a new delivery system presents a high degree of complexity, the assessment of its quality, efficacy and safety is challenging for regulatory authorities. It is the case of innovative nanomedicines that have been developed and marketed over the past half-century, revolutionizing the prognosis of many human diseases. Indeed, due to the intrinsic high structural complexity of these products, the scientific and regulatory communities have been pushed in reflecting on how to revise the regulatory framework to provide a more appropriate benefit/risk balance to authorize them on the market, considering the impact of their peculiar physicochemical features in the efficacy and safety patterns. Herein, a critical perspective is provided on the current open issues regarding regulatory qualification and physicochemical characterization of nanosystems considering the current European regulatory framework on nanomedicine products. Practicable paths for improving their quality assurance and predicting their fate in vivo are also argued. Strengthening the multilevel alliance among academic institutions, industrial stakeholders, and regulatory authorities seems strategic to support innovation by standard approaches (e.g., qualification, characterization, risk assessment), and to expand current knowledge, also benefiting from the new opportunities offered by artificial intelligence and digitization in predictive modelling of the impact of nanomedicine characteristics on their fate in vivo.