Nanomedicines: The magic bullets reaching their target?

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Abstract

Nanomedicines, since the approval of the first one in the 1950s, have been accompanied by expectations of higher efficiency and efficacy, compared to less complex drugs. The fulfilment of those expectations has been slower than anticipated, due to the high complexity of nanomedicines drugs combined with a lack of scientific understanding of nanomedicines interactions with the biological systems. The unique properties of their size and their surface composition, which creates difficulties in their physicochemical characterization, and as a consequence, difficulty in assessing the similarity of follow-on products (nanosimilars) to originator nanomedicines. During the 2018 European Federation for Pharmaceutical Sciences (EUFEPS) annual meeting “Crossing the barrier for future medicines” in Athens, there were several sessions on nanomedicines organised by the EUFEPS Nanomedicine Network. This review focuses on the session “Nanomedicines and nanosimilars: how to assess similar?”, discussing the nature of nanomedicines, the regulatory aspects of the topic and the impact of practical use and handling of such medicinal products. Emphasis is put on the consequences that their nanosize-related properties has on the establishment of their critical quality attributes and how this affects the demonstration of bioequivalence of nanosimilars to their originator products. The lack of an appropriate and harmonized regulatory evaluation procedure and the absence of corresponding education are also discussed, especially the uncertainty surrounding the practical use of nanosimilars, including the higher healthcare cost due to less than satisfactory number of safe and efficacious nanosimilars in the market.

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