# Tackling the challenges of nanomedicines: are we ready?

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**Abstract**

**Purpose**
This review provides an overview of the proceedings of the symposium “Tackling the Challenges of Nanomedicines: Are We ready?” organized by the International Pharmaceutical Federation (FIP)Hospital Pharmacy Section and Non-Biological Complex Drugs (NBCDs) Working Group at the 2019FIP World Congress of Pharmacy and Pharmaceutical Sciences. Debate centered on reasons underlying the current complex regulatory landscape for nanomedicines and their follow-on products (referred to as nanosimilars) and the pivotal role of hospital pharmacists in selecting, handling, and guiding usage of nanomedicines and nanosimilars.

**Summary**
The evaluation and use of nanomedicines are recognized among scientific, pharmaceutical, and regulatory bodies as complex. Interchangeability and substitutability of nanomedicines and nanosimilars are confounded by a lack of pharmaceutical and pharmacological equivalence, reflecting the inherent complex nature of these drug products and manufacturing processes. Consequences include implications for clinical safety and efficacy and, ultimately, comparability. Local regulatory approvals of some nanomedicines have occurred, but there is no standard to ensure streamlined evaluation and use of consistent measures of therapeutic equivalence of reference products and their nanosimilars. Hospital pharmacists are expected to be experts in the selection, handling, and substitution of nanomedicines and familiarize themselves with the limitations of current methods of assessing pharmaceutical and clinical equivalence of nanosimilars in order to ensure informed formulary decision-making and eventual patient benefit.

**Conclusion**
Supportive guidance for pharmacists focusing on the substitutability and/or interchangeability of nanomedicines and their nanosimilars is needed. Current FIP guidance for pharmacists on therapeutic interchange and substitution should be extended to include nanomedicines and nanosimilars.

**Keywords:** nanomedicine, nanosimilars, pharmacists, substitution, therapeutic equivalency

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