How to select a nanosimilar

Alain Astier[1], Amy Barton Pai[2], Marco Bissig[3], Daan JA Crommelin[4] , Beat Flühmann[5], Jean-Daniel Hecq[6] , Josefien Knoeff[5,7] ,Hans-Peter Lipp[8] , Alberto Morell-Baladaron[9] and Stefan Mühlebach[5,10]

[1]*Department of Pharmacy, Henri Mondor University Hospitals, Créteil, France.*
[2] *Department of Clinical Pharmacy, University of Michigan, Ann Arbor, Michigan, USA.*
[3]*Hospital Pharmacy, Ospedale Regionale di Lugano, Lugano, Switzerland.*
[4]*Department of Pharmaceutical Sciences, Utrecht University, The Netherlands.*
[5]*Vifor Pharma Ltd., Glattbrugg, Switzerland.*
[6]*Hospital Pharmacy, University Hospital of Mont-Godinne, Yvoir, Belgium.*
[7]*Faculty of Sciences, Vrije Universiteit Amsterdam, the Netherlands.*
[8]*Hospital Pharmacy, Universitätsklinikum Tübingen, Germany.*
[9]*Hospital Pharmacy, La Princessa Hospital, Madrid, Spain.*
[10]*Department of Pharmaceutical Sciences, University of Basel, Basel, Switzerland*

Abstract

Nanomedicines in the class of nonbiological complex drugs (NBCDs) are becoming increasingly available. Up to 23 nanomedicines have been approved, and approximately 50 are in clinical development. Meanwhile, the first nanosimilars have entered the market through the generic approval pathway, but clinical differences have been observed. Many healthcare professionals may be unaware of this issue and must be informed of these clinically relevant variances. This article provides a tool for rational decision making for the inclusion of nanomedicines into the hospital formulary, including defined criteria for evaluation of substitutability or interchangeability. The tool was generated by conducting a roundtable with an international panel of experts and follows the same thought process that was developed and published earlier for the selection of biologicals/biosimilars. In addition to the existing criteria for biosimilars, a set of seven criteria was identified that specifically apply to nanosimilars. These include (1) particle size and size distribution, (2) particle surface characteristics, (3) fraction of uncaptured bioactive moiety, (4) stability on storage, (5) bioactive moiety uptake and (6) distribution, and (7) stability for ready-to-use preparation. Pharmacists should utilize their pharmaceutical expertise to use the appropriate criteria to evaluate the comparability of the drug to decide on interchangeability or substitutability.

Published in : Ann N Y Acad Sci. 2017 Jul 17. doi: 10.1111/nyas.13382. [Epub ahead of print]
Contact: beat.fluehmann@viforpharma.com