Ann N Y Acad Sci. 2017 Apr 26. doi: 10.1111/nyas.13347. [Epub ahead of print]

Equivalence of complex drug products: advances in and challenges for current regulatory frameworks.

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Abstract

Biotechnology and nanotechnology provide a growing number of innovator-driven complex drug products and their copy versions. Biologics exemplify one category of complex drugs, but there are also nonbiological complex drug products, including many nanomedicines, such as iron-carbohydrate complexes, drug-carrying liposomes or emulsions, and glatiramoids. In this white paper, which stems from a 1-day conference at the New York Academy of Sciences, we discuss regulatory frameworks in use worldwide (e.g., the U.S. Food and Drug Administration, the European Medicines Agency, the World Health Organization) to approve these complex drug products and their follow-on versions. One of the key questions remains how to assess equivalence of these complex products. We identify a number of points for which consensus was found among the stakeholders who were present: scientists from innovator and generic/follow-on companies, academia, and regulatory bodies from different parts of the world. A number of topics requiring follow-up were identified: (1) assessment of critical attributes to establish equivalence for follow-on versions, (2) the need to publish scientific findings in the public domain to further progress in the field, (3) the necessity to develop worldwide consensus regarding nomenclature and labeling of these complex products, and (4) regulatory actions when substandard complex drug products are identified.

KEYWORDS:

EMA; FDA; biosimilar; complex drug; generics; nonbiological complex drugs (NBCDs); pharmaceutical; regulatory science; therapeutic equivalency