Different pharmaceutical products need similar terminology

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Abstract

In the last decade, discussions on the development of the regulatory framework of generic versions of complex drugs such as biologicals and non-biological complex drugs have attracted broad attention. The terminology used is far from harmonized and can lead to multiple interpretations of legal texts, reflection papers, and guidance documents regarding market introduction as well as reimbursement. This article describes the meaning of relevant terms in different global regions (Europe, USA, WHO) and offers a proposal for a globally accepted terminology regarding (non-) biological complex drugs.

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