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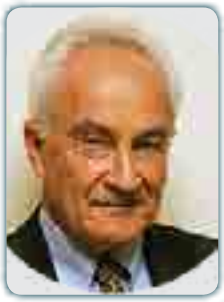

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Interchangeability, switch ability and substitution of biosimilar drug products

The assessment of and conditions for the interchangeability of biological and small-molecule drug products are very different. Small-molecule drugs are well defined and can be exactly reproduced. If their products, brand-name and generic, are declared to be bioequivalent then they are (most frequently but not always) therapeutically equivalent and can be substituted and interchanged. In contrast, biological drugs are structurally and functionally complicated, can be only imitated but not identically reproduced, are sensitive to various environmental and manufacturing conditions, are subject to biological and immunological influences. Consequently, only high similarity but not equivalence can be demonstrated, in various respects, between the marketed and new products. However, even the stated bio similarity of two products does not enable their interchangeability in terms of switching and alternating. For this, additional conditions must be satisfied. There has been no agreement on these conditions among the various jurisdictions. Legislation in the United States, and also FDA, has set general principles. The European EMA has issued biosimilarity guidelines for several drug products. The latter permit in some cases possible interchangeability even though the issue is under the judgment of the member states. It is desirable to develop a general, scientific basis for the evaluation of interchangeability of biological drug products. Suitable study designs are considered, an approach for the assessment of switching and alternating across multiple domains is presented, and a possible criterion for the interchangeability of biological products is described.

Biography

Laszlo Endrenyi is a Professor Emeritus of Pharmacology and Biostatistics in the University of Toronto. He has served the university in various positions including on its Governing Council and as Associate Dean of Graduate Studies. He sat on the Board of Directors of the American Statistical Association and the Canadian Society for Pharmaceutical Scientists. He served as President of the latter and received its Lifetime Achievement Award. Externally, he has served on grant review committees and editorial boards of research journals. He has received several recognitions, including an honorary doctorate from the Semmelweis University of Medicine. He is a Fellow of the Canadian Society for Pharmaceutical Sciences and of the American Association of Pharmaceutical Scientists. He has published books on Kinetic Data Analysis and Biosimilar Drug Product Development, and over 200 research papers. He has advised and widely consulted with industry and regulatory agencies.

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