

Generic versus Brand Name Anticoagulants: What Does the Future Hold?

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Conventional anticoagulant drugs such as unfractionated heparin, warfarin and aspirin are currently available in their generic forms for clinical usage. To a large extent these agents are considered clinically equivalent. However, safety and efficacy issues have been raised with the use of some of the generic versions of these products. In particular, several problems related to the safety and efficacies have been noted with unfractionated heparin, which includes lack of anticoagulant efficacy and bleeding. Because of the heterogeneous nature of this drug and its origin routine standardization methods failed to recognize such problems as the origin, contaminants and purity. The issues with warfarin and aspirin are not as complex and may require further investigations.

More recently the generic versions of such LMWHs as enoxaparin have been developed. Although there is no approved generic enoxaparin available at this time, several generic companies have submitted applications to the FDA to market generic versions of this LMWH. Because of the complex nature of this drug, which includes both the biologic and chemical factors, the current guideline for its approval is not valid.

Knowing this, the concept of biosimilars is introduced. Although the term is well defined there are no firm guidelines for the approval of these drugs. Moreover, there is a strong debate on the relative safety and efficacy of generic LMWHs. Fondaparinux represents synthetic oligosaccharides with anticoagulant effects. More recently, a generic version of fondaparinux has been developed. However, because of its structural complexity it may not be approved through classic generic pathways. Generic versions of parenteral antithrombin agents such as argatroban, angiomax and hirudin also have been developed. Because of the critical nature of these drugs, safety and efficacy remains an issue with their generic versions as well.

Until proper guidelines are developed for each of these anticoagulant drugs, patient safety will remain a concern. Unlike other drugs, the anticoagulant agents are used in multiple indications. Therefore their safety and efficacy should be adequately demonstrated prior to their approval, thus the conventional guidelines for the approval of generic drugs may not be applicable to anticoagulants, in particular the complex biologics such as heparins and their derivatives.