Structure and Haemostatic Effects of Generic Versions of Enoxaparin Available for Clinical Use in Brazil

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Patent protection for enoxaparin has expired. Generic preparations are developed and approved for clinical use in different countries. However, there is still skepticism about the possibility of making an exact copy of the original drug due to the complex processes involved in generating low-molecular-weight heparins. We have undertaken a careful analysis of generic versions of enoxaparin available for clinical use in Brazil. Thirty three batches of active ingredient and 70 of the final pharmaceutical product were obtained from six different suppliers. They were analyzed for their chemical composition, molecular size distribution, in vitro anticoagulant activity and pharmacological effects on animal models of experimental thrombosis and bleeding. Clearly, the generic versions of enoxaparin available for clinical use in Brazil are similar to the original drug. Only three out of 33 batches of active ingredient from one supplier showed differences in the molecular size distribution. This is due to a low percentage of tetrasaccharide or the presence of a minor component eluted as monosaccharide. Three out of 70 batches of the final pharmaceutical products contained lower amounts of active ingredient than declared by the suppliers. Our results suggest that the generic versions of enoxaparin are a viable therapeutic option, but their use requires strict regulations to ensure accurate standards.

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