How Similar are the Generic Versions of Enoxaparin Available for Clinical Use in Brazil to the Original Drug?

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Patent protection for enoxaparin has expired. Generic preparations have been developed and approved for clinical use in several 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 39 of the final pharmaceutical product were obtained from five different suppliers. They were analyzed for their chemical structure, 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 due to a low proportion of tetrasaccharide or the presence of an unknown component eluted as monosaccharide. Three out of 39 batches of the final pharmaceutical products contained lower amounts of active ingredient than declared by the suppliers. Our results indicate that the generic versions of enoxaparin are a valid therapeutic alternative, but their use requires strict regulations to ensure precise standards. Financial support: CNPq and FAPERJ.