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POSTER COMMUNICATION · HOSPITAL & CLINICAL PHARMACY

Evaluation of commercially available low molecular mass heparin products: an internal market surveillance study

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KEY MESSAGES

1. Tous les échantillons testés respectent les spécifications pharmacopéiales pour l'activité anti-Xa.
2. Aucune activité atypique n'a été observée parmi les produits évalués.
3. La surveillance du marché est essentielle pour garantir la qualité des produits LMWH.

ABSTRACT

Introduction. Low molecular mass heparins (LMWHs) are complex biological products with activity profiles dependent on source material and manufacturing. Differences exist within the same therapeutic class, and the 2007-2008 contamination crisis highlighted the need for robust analytical control. Post-marketing surveillance complements pre-authorization quality assessment by providing direct evidence of product quality available to patients.

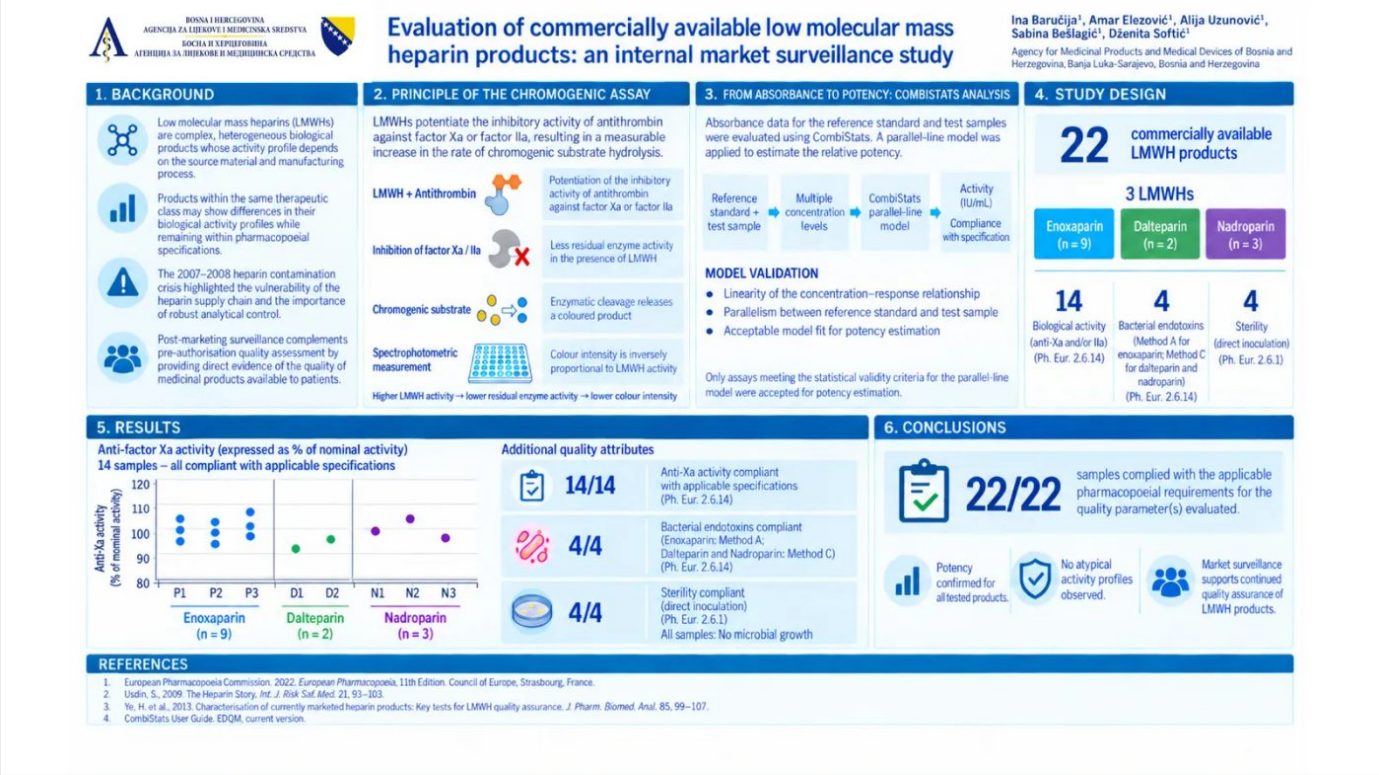
Materials and methods. The study evaluated 22 commercially available LMWH products (Enoxaparin, Dalteparin, Nadroparin) using a chromogenic assay measuring antithrombin activity against factor Xa or IIa. Absorbance data were analyzed with CombiStats software applying a parallel-line model to estimate relative potency. Additional quality attributes assessed included biological activity, bacterial endotoxins, and sterility according to European Pharmacopoeia methods.

Results. All 14 tested samples complied with specifications for anti-factor Xa activity. Additional quality attributes showed full compliance: 14/14 for anti-Xa activity, 4/4 for bacterial endotoxins, and 4/4 for sterility with no microbial growth. Potency was confirmed for all tested products with no atypical activity profiles observed.

Conclusion. All 22 LMWH samples complied with applicable pharmacopoeial requirements for quality parameters evaluated. Market surveillance supports continued quality assurance of LMWH products.

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