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UK firm withdraws insulin marketing applications

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UK firm withdraws insulin marketing application to comply with new EMA guidelines

Singapore: UK's Marvel LifeScience, insulin marketing company, has withdrawn its application for centralized marketing authorizations for the medicines Solumarv, Isomarv and Combimarv (human insulin), all 100 IU/ml solution for injection. They were intended to be used for the treatment of patients with diabetes mellitus, who require insulin for the maintenance of glucose homeostasis.

The medicines were developed as biosimilars. The applications for the marketing authorization for Solumarv, Isomarv and Combimarv were submitted to European Medicines Agency (EMA) on December 5, 2011. At the time of the withdrawal, all three medicines were under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter to the EMA the company stated that, "The decision to withdraw is in order to have sufficient time to repeat and submit bioequivalence type 1 diabetes pharmacokinetic and pharmacodynamic data on each clamp study so as to comply with the planned new insulin guideline at a validated contract research organization (CRO)."