ABSTRACT

Title: Post-authorisation safety study of the incidence rate of medication errors before and after the discontinuation of the lower strength vials for Pharmalgen.

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Keywords: PASS, Pharmalgen, medication error, allergy immunotherapy, dilution

Rationale and background: Pharmalgen is a product line indicated for venom immunotherapy administered by subcutaneous injection. The administered doses are increased gradually through up-dosing until a maintenance dose is reached. Due to discontinuation of the lower strengths of Pharmalgen (vial 1, 0.12 µg; vial 2, 1.2 µg; vial 3, 12 µg) previously used for preparation of doses for up-dosing, the preparation protocol was changed to all doses being prepared from the highest strength (vial 4, 120 µg) via dilution.

Research question and objectives: The purpose of this study was to characterize safety of Pharmalgen products after discontinuation of the lower strength vials to evaluate if an increase in medication errors or systemic allergic reactions related to medication errors occurred during the up-dosing phase.

Study design: Non-interventional post-authorisation safety study in the form of a prospective descriptive case study.

Setting: Study involving post-marketing reports which has been received, processed and submitted by ALK Global Pharmacovigilance.

Subjects and study size, variables and data sources: This study includes all relevant adverse event reports received from the United Kingdom from spontaneous sources concerning patients in treatment with Pharmalgen (801) *Apis mellifera* or Pharmalgen (802) *Vespula* spp.

Results: During the study period - covering two years following discontinuation of the lower dose vials - one case concerning a medication error was received from the UK. The case concerned a patient who had been administered a wrong dose due to an error made in the dilution procedure by the administering nurse. The case received corresponds to an adverse event rate of 0.10% (95% CI: [0.0026%; 0.58%]) for Pharmalgen (801) *Apis mellifera* and Pharmalgen (802) *Vespula* spp. vial 4 combined, and 0.27% (95% CI: [0.0069%;1.50%]) for Pharmalgen (801) *Apis mellifera* vial 4 specifically. As this case is the first medication error received from the United Kingdom for Pharmalgen, the cumulative reporting rate of 0.022% (95% CI: [0.001%;0.13%]) for Pharmalgen (801) *Apis mellifera* and (802) *Vespula* spp. vial 4 is based on the same case.

Discussion: The assessment of the significance of the number of cases received during the study period is complicated by the fact that no medication errors have been received historically from the United Kingdom prior to this study. Even a small number of received cases therefore represents a significant increase in the reporting rate. Although a statistical analysis of historical data for similar situations resulted in an expectation of 0 cases being received for both scenarios relevant for this report, the sponsor considers the number of received cases (one) for medication errors and the resulting reporting rate to be an acceptable result for the product.

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