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The impact of Pharmacovigilance in Patient Support Programs for Orphan Diseases, experience in Spain

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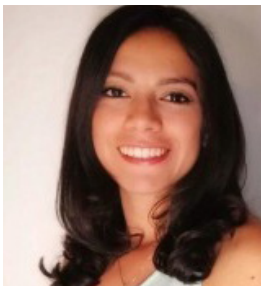

Author Biography

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Strong expertise in Pharmacovigilance in clinical studies, patient support programs, rare diseases, and marketed products, performing tasks as monitoring, reviewing, analysis, coding and data entry information of adverse events in accordance with standard operating procedures and product standards, reporting all information to the FDA, EMEA and / or other regulatory agencies to ensure the objectives of timeline, quality and productivity. Training and support in Pharmacovigilance programs. Physical Therapist with Master in Business Administration.

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NThe pharmacovigilance (PV) of drugs for orphan diseases present problems related to the small patient population. Obtaining high-quality information on individual reports of suspected adverse reactions is of particular importance for the PV of orphan drugs (Price J, 2016).

On the other hand, Patient Support Programs (PSPs), according to Good Vigilance Practices (GVP)-Module VI, involve direct interaction with patients or patient carriers for the purpose of helping to manage a patient's medication or disease outcomes (e.g., adherence, awareness, education) (Leporini C, et al, 2014), and providing healthcare professionals with support. In the frame of those aspects, the implementation and articulation of a Pharmacovigilance program has been described with focus in case management, procedures and Pharmacovigilance culture: drug administration education, Adverse Drug Reactions (ADR) knowledge, HCP training. Purpose: To conduct a targeted review describing the impact of pharmacovigilance program development in a PSP in Spain, regarding to improving clinical and adherence.

Data source: Database PSP: Anderson-Fabry disease, Gaucher disease, Hereditary Angioedema, Primary Immunodeficiency Syndrome and Hemophilia. Methods: A retrospective 12-month analysis was conducted to compare treatment adherence and medical outcomes in patient with PSP and Pharmacovigilance Program versus those who did not enroll using linkage algorithm based on probabilistic matching was developed to link the PV database to the PSP. Findings: The analysis of 120 patients showed statistically significant differences in the probability of adherence to treatment in relation to the patients who were part of the PSP and the Pharmacovigilance, in comparison with the patients who did not participate. It was found that patients within the programs have a 72% lower risk of interruption of therapy (risk index = 0.282, P <0.0001), and a greater probability of being adherent (probability index = 1.483; P <0.0001), compared to those patients who are not included in the programs. The dropout rate at the start of treatment was significantly higher in patients who did not participate in any program (P <0.0001). Conclusions: Patient adherence is crucial to quality healthcare outcomes (Farmer, K.C, 2009).; however, achievement of consistent adherence remains difficult. Patient non-adherence represents an important health problem, from a clinical/economic viewpoint(Luzzatto, L.A, 2015), being associated with reduced treatment benefits. A complete PV Program articulated with PSP activities, were associated with greater patient persistence and adherence over the first 12 months of treatment. Careful assessment of this relationship is crucial in planning for interventions needed to improve effectiveness of pharmacological care and to safeguard sustainability of healthcare systems with an impact in the patient with rare diseases.

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