

医薬品の適正使用推進のための製造販売後調査の重要性について — 塩酸タムスロシンの製造販売後調査の例 —

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The Importance of Post Marketing Surveillance (PMS) to Promote the Proper Use of Pharmaceutical Drugs — Lesson from PMS of Tamsulosin Hydrochloride —

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Abstract

For pharmaceutical manufacturers, it is necessary to collect information about adverse events and evaluate them in Post Marketing Surveillance (PMS). Furthermore, it is important to promote the proper use of pharmaceutical drugs by offering this information to medical workers adequately.

Medication for patients with renal impairment by using Tamsulosin Hydrochloride (Harnal®) was listed as “contraindication” in Japan. However, the findings from clinical experiences after marketing were re-evaluated so that the word of “patients with renal impairment” was deleted from the section of [contraindication] on the attached document. This is one example which the proper use of pharmaceutical drugs based on PMS was promoted.

We introduce the necessity and the importance of PMS to promote the proper use of pharmaceutical drugs with showing those processes.

Key words: tamsulosin hydrochloride, renal impairment, Post Marketing Surveillance (PMS), proper use, α_1 -Acid Glycoprotein (α_1 -AGP)