

緊急安全性情報の波及効果 — 副作用報告に関する調査 —

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Effect of emergency safety information(doctor letters) — survey on adverse drug reaction reports —

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Abstract

Objective: This study aimed to examine the effects of emergency safety information on the number of adverse drug reaction reports.

Methods: We selected the following cases from emergency safety information: (1) cases in which the period between product launch and issuance of emergency safety information was long: interstitial pneumonia from *shosaikoto* (9-year period before the issuance of emergency safety information); and fulminant hepatitis from benzbromarone, (20-year period); (2) case in which the period between product launch and issuance of emergency safety information was short: heart failure from pioglitazone, (1 year and 8 months). We then chronologically analyzed the number of adverse drug reaction reports using the PMDA case information website, and examined the number of adverse drug reaction reports available on Ichushi Web.

Results: Findings showed that reports of interstitial pneumonia from *shosaikoto* continued to be made for 15 years, beginning in 3 years following on sale. Accordingly, production of the drug declined to 1/6 of its initial distribution during that period. Fulminant hepatitis from benzbromarone was first reported 2 years prior to issuance of its emergency safety information, and was reported 1 to 3 times a year in the 5-year period following its issuance. On the other hand, even though there were no reports of heart failure from pioglitazone in the product's initial year of sales, the number of reported cases jumped to 60 in the second year and continued to stay at 30 to 40 a year in the following period. Despite these reports, sales of the drug quadrupled during this period.

Conclusion: This study found that issuance of emergency safety information prompted a certain level of awareness of appropriate drug usage by drawing attention to potential adverse drug reactions, which in turn resulted in a temporary increase in the number of adverse drug reaction reports. The number of reports did not decrease drastically over time, and adverse reactions continued to be reported.

Key words: emergency safety information, adverse drug reaction report, PMDA website, Ichushi Web