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Impact of rosiglitazone safety alerts on oral antidiabetic sales trends: a countrywide study in Portugal.

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Abstract

Pharmacovigilance systems are important to monitor the safety of on-market drugs after approval. The aim of this study was to assess the impact of rosiglitazone safety alerts on trends in the sale of rosiglitazone and other oral antidiabetic drugs. An ecological study was conducted, using temporally aggregated data and linking safety alerts to countrywide sales of all oral antidiabetic drugs in Portugal from January 2002 to December 2012. Sales figures for oral antidiabetic drugs marketed in Portugal were supplied by IMS Health Portugal with a breakdown by active substance and fixed combinations. The number of defined daily doses per 1000 inhabitants per day (DIDs) of each oral antidiabetic drug sold to the estimated diabetic population using oral antidiabetic drugs in Portugal was calculated. Particular attention was paid to the case of rosiglitazone, with the results being adjusted for changes in rosiglitazone reimbursement policies. A total of four safety alerts were issued about rosiglitazone. Rosiglitazone sales registered an increase of 32.9% (0.202 DIDs; $P < 0.001$) after the first alert (risk of macular oedema or worsening of pre-existent macular oedema) in January 2006. After subsequent alerts about cardiovascular risks, this trend was not, however, repeated and sales fell. Following the January 2006 and January 2008 safety alerts, rosiglitazone sales described a long-term downward trend, with decreases of 3.75% (-0023 DIDs; $P > 0.05$) and 0.24% (-0.001 DIDs; $P > 0.05$), respectively. It is important to promote the dissemination and publication of drug safety alerts.

KEYWORDS: oral antidiabetic drugs; rosiglitazone; safety alerts; sale trends

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