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Oral Presentations

O.09 The Influence of Notoriety Bias on ADR Spontaneous Reporting Rate

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Background: The reporting of adverse drug reactions (ADRs) by doctors and other health personnel is the mainstream of the post-marketing surveillance systems. Underreporting and selective reporting are considered the main limitations of a spontaneous reporting-based pharmacovigilance system. However, also an excessive reporting, induced by external influences, may impair the signal detection, by increasing the noise level.

Objective: The aim of this study was to assess the influence of media, medical journals and regulatory decisions on the rate of adverse drug reaction reporting. We focused on four typical situations occurred in Italy and/or Europe: ACE inhibitors-induced cough and restriction of angiotensin receptor blockers (ARB) reimbursement, statins and rhabdomyolysis, nimesulide and hepatic toxicity, and COXIBs and cardiovascular risk.

Methods: The study was based on data coming from spontaneous reporting in six Italian Regions collected from January 1995 to December 2005. We analysed a 10 year period as a reasonable time interval focusing on the influence of external factors on the rate of ADR reporting. Drug sales data were also considered to assess the possible changes of drug use. Sales data were expressed as daily defined dose (DDD) per 1000 inhabitants per day.

Results: *ACE inhibitors*: an increase of about four-fold in the number of reports of ACE inhibitor-induced cough was observed in 1998-1999 following the restriction of ARB reimbursement. In the same period sales of ARBs strongly increased whereas ACE inhibitors increased only slightly. *Statins*: the percent of ADRs of rhabdomyolysis increased about 5-fold after the "Lipobay scandal" in 2001 and progressively decreased in the following years. The sales of these drugs increased from 2000 to 2005. *Nimesulide*: an increase of hepatic ADR reporting was observed after withdrawal of the drug from Finnish and Spanish markets in 2002, without any effects on sales. *COXIBs*: a modest increase of cardiovascular ADR reporting was observed after rofecoxib withdrawal in 2004, with a sharp drop of both sales and ADR reports in 2005.

Conclusion: Post-marketing pharmacovigilance systems play a key role in the assessment of drug risk/benefit profile, however underreporting, selective reporting and the notoriety bias can influence the early detection of new signals and their interpretation. This analysis also emphasised the importance of adopting appropriate risk communication strategies as a crucial part of health policy, agreed by health regulatory bodies, drug manufacturers and doctors, ensuring in the meantime independent and appropriate information to the patients.