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Adverse drug reaction reporting activities of Pharmaceutical companies in Vietnam from 2014-2015: a cross-sectional study

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Summary: *In Vietnam, majority of management and research activities in pharmacovigilance has primarily focused on health facilities while those for pharmaceutical companies has been limited. This study therefore aims to study on ADR reporting activities of pharmaceutical companies, based ondata from the National Pharmacovigilance database.According the study results, the number of ADR reports submitted by pharmaceutical laboratories was still limited (contributed to only 7.5%-8% of the total number of ADR reports) and the quality of ADR reports was generally low. However, despite these limitations, the ADR reports submitted by pharmaceutical companiesshould be still recognized as a valuable information source because majority of these reports focused on reporting serious (80.1%), uncertain (97.5%) ADRs. Besides, our observation on its reporting pattern also indicated that the rate of ADR which requires clinical monitoring and laboratory tests to detect as well as the rate of drugs for chronic treatment reported in the study sample were high, which were different from previous studies on health facilities reporitng system. Last but not the least, Last but not the least, our study also found that the reporting trend during the release of the National Pharmacovigilance guideline in 2016 seemed to be more stable incomparison with this observed in the previous years through an analysis using the segmented regression model.*