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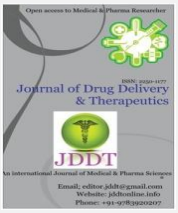

Open Access CASE STUDY

Consumer Adverse Drug Reactions (ADRs) Reporting in Malaysia: A Retrospective Analysis of Spontaneous Reports from the National Pharmacovigilance Database from 2008 to 2015

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ABSTRACT

Many countries are incorporating direct patient reporting of adverse drug reactions (ADRs) into their pharmacovigilance systems as patients provide a different insight into drug safety compared to healthcare professionals. In Malaysia, consumer reporting of ADRs and issues with product qualitiesbegan in 2007.The aim of this study was to examine consumer reports in terms of ADR categoriesby System Organ Class (SOC), suspected products and the seriousness of the ADRs.

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METHODS:

The Malaysian Pharmacovigilance database was retrospectively searched from 2008 to 2015 to identify consumer reports. We excluded reports of adverse events following immunisation, and descriptively analysed eligible reports using SPSS version 20. Chi-squared test with significance level ofp < 0.05 was used to evaluate the association of various categorical variables with serious ADRs.

FINDINGS:

Out of the 101,957 ADR reports available in the National ADR database for the period 2008 to 2015, only 81 (0.08%) reports were by consumers. The majority (64%) of the consumer reports used the consumer reporting form while a small proportion used ADRs form designed for healthcare professionals. Almost half of these 81 reports involved complementary and alternative medicines (CAM)while other major classes of products involved were prescription medicines (19%) and cosmetics (11%). Of the total ADRs reports, the three main SOC involved were skin and appendages disorders (26%), body as a whole (25%), and central and peripheral nervous system disorders (9%). The Malaysian Pharmacovigilance Centre obtained and tested 45samples, of which 19(42%) were CAMs products found to be adulterated with prescription drugs while 4 cosmetic productsexceeded the permitted limit for hydroquinone or mercury. More than half of the reports involved unregistered products or unapproved cosmetics. Two factors found to be significantly associated with serious ADRs were status of product registration and presence of product adulteration.

CONCLUSION:

Our preliminary findings show that consumers have the potential to provide valuable feedbackparticularly for serious ADR reports. The National Centre should allocate specific resources for the assessment of consumer reports to strengthen pharmacovigilance.