Meetings International SciTechnol

Shereen Aly, J Addict Behav Ther Rehabil 2018, Volume: 7
DOI: 10.4172/2324-9005-C3-013

WORLD DRUG DELIVERY AND NOVEL THERAPY SUMMIT

&

Annual Congress on

NEUROSCIENCE & THERAPEUTICS

October 25-26, 2018 | Toronto, Canada

Shereen Aly

MD Pharma Consulting Group, Canada

Impact analysis of mandatory reporting of serious adverse drug reactions and medical device incidents on healthcare institutions following the 2014 amendment to the food and drug regulations (Vanessa's Law) in Canada

The study measures the national readiness of acute healthcare institutions for the adoption and implementation of the serious adverse event and medical device incident mandatory reporting process to meet the new Canadian drug law; Protecting Canadian from Unsafe Drug Act "Vanessa's Law" set by Health Canada. An online survey questionnaire was designed to gain institutional insights on policy awareness, preparedness, systems and processes, resourcing and training measures taken for adverse event reporting and the potential challenges and benefits that would be faced when the law becomes implemented in December 2019. Analysis of the results indicated that 96.4 % of the respondents were unaware of Vanessa's Law and its reporting requirements, 50% of respondents confirmed the preparedness of their respective institutions to implement the new ADR reporting requirement. In regards their information management sytems, 75% of respondents indicated they have a well-established reporting system in place to support the new regulation. Currently, ADR reporting within the healthcare institutions is an encouraged voluntary process. It has been identified that awareness of the new law is very low with no clear supporting guidance in place yet. Hospitals need a formal guidance from Health Canada upon which to base their operational procedures and in order to ensure that institutions can develop appropriate training and standard operational procedures for the reporting of mandatory ADR and medical device incidents. Health Canada needs to consider immediately implementing educational strategies to address this issue as well as a clear and descriptive supporting guidance before the law goes into full force.

Biography

Shereen Aly is a Physician & Pharmacovigilance expert. She received her Master and PhD degree in Critical Care Medicine in 2007 and also a holder of a master degree in pharmacovigilance and epidemiology from 7 affiliated European Universities under the EU2p Program. She is a true pioneer in her field and an author of many scientific publications. Her role focuses on being a medical advisor to healthcare providers, industry and regulatory agencies. Her priority is Post- Market drug surveillance relating to the collection, detection, assessment, monitoring and prevention of adverse effects with pharmaceutical products.

shereenali@hotmail.com

Notes: