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Pharmacovigilance through social media- A newer insight

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REVIEW ARTICLE

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ABSTRACT

The proposed review provides an insight into the use of social networks for fruitful generation of the data for the safe and effective use of drugs. It is worth mentioning that the uninhibited use of platforms like Twitter, Face book, Forums could be harnessed for better healthcare at reduced prices for better economic perspective.

The method used is in-silico programmed based techniques which identify the words which are medically correct and moreover associated with the patients are then reported to the regulatory authorities.

The collation of the data based on social jargon selected from aforementioned social platforms has been systematically arranged, filtered and processed to generate data which can be effectively used for mitigation of side effects, adverse reactions and ultimately reducing the hospital stay of the concerned patients. This process has recently gained popularity and acceptability among regulatory authorities like US FDA.

With the imminent internet revolution in place and positive government policies in making use of the virtual programmes, the day is not far away where the social platforms would be used successfully to generate health care and safety data thus providing greater insights about the drug that is marketed by the pharmaceutical companies.

INTRODUCTION

As the world of technology is growing, the reach of an ordinary man has also evolved with information in his hands within a click. The use of digital media and print media are the talking platforms for various issues and the opinions one has regarding the emerging issues of the country or their personal life (Valenzuela, 2013). Social media such as Twitter, LinkedIn, Facebook, Forums are common points of discussions for people having the same thought process. These online conversations are mainly used for the promotion of the commercial products, their improvement and innovations; the pharmaceutical industry or the health industry has not been untouched to this platform of public engagement.

Reporting of the harmful reactions occurred due to intake of the medications is termed as the adverse drug reaction (ADR) (Karch & Lasagna, 1977). The detection, monitoring and assessment of the ADRs are known as Pharmacovigilance (Härmark & Van Grootheest, 2008).

Various regulatory authorities such as Food and Drug Administration (US FDA) have been looking closer into the identification of the ADRs (Klepper, 2004). On the launch of a new product, post marketing surveillance report is submitted to the regulatory authorities by the biopharmaceutical companies so as to get the Market authorization for selling their product. This trend is also applied to the drugs which are in the advanced phase of the clinical trial (Meyboom, 1999). In Pharmacovigilance, these data reports are generally prepared with the insights from the physicians, the healthcare professionals or the pharmacies located within the region.

Can Social Media be used for Pharmacovigilance?

Social Media is the emerging methodology for the pharmaceutical companies to shift from the

traditional PV systems and safety reporting methods towards more patient-centric models for analyzing, monitoring and reporting safety data. These social platforms have the capacity for direct and open communications between the patients/consumers and healthcare providers regarding the use of medicinal products, thereby helping promoting transparency and building public trust (O'Connor, 2016).

Social media monitoring will eventually become a standard practice in PV in the near future. However, before that, careful evaluation and assessment of the use of social media as a PV tool needs to be considered; both in terms of meaningfulness and impact on results. Further, assessment of the regulations and laws are needed for effective use on big data extracted via social media channels with their cost of use and overall cost-benefit analysis needs to be assessed.

Regulatory Guidance on Use of Internet and Social Media in PV

Pharmaceutical companies in UK comply with requirements of the regulatory authorities such as "Association of the British Pharmaceutical Industry" (ABPI) Code of Practice for Pharmaceutical Industry and guidance on digital communications, given by the Prescription Medicines Code of Practice Authority (PMCPA) (Gibson, 2014). The PV legislation has two aspects in Europe: Directive 2001/83/EC (as amended by Directive 2010/84/EU) and Regulation 726/2004 (as amended by Regulation 1235/2010).Operational aspects are mentioned in the GVP Module VI which refers to the fact that Marketing Authorization Holders should scan and screen the social media platforms with responsibility and management and look for adverse effects/reactions. The reporting of these adverse reactions to the competent authorities should identify the potential and valid individual case safety reports (ICSRs) and should be reported within the given time limit, thereby mentioning the date when the event was posted on the internet or the social media platforms (Sloane , 2015).

The US Food and Drug Administration (FDA) have published 3 documents about product promotion on social media and the Internet by pharmaceutical and medical device companies. The FDA guidance highlights the role of biopharmaceutical companies on the reporting of the off-label usage of the medicines and also its inquiry which are originating from the digital platform.The next guidance suggests that the pharmaceutical and the device companies should advantages as well as the risks involved in-take of the medicines on the Internet and other digital platforms within the word limit (Eg. Twitter). The last guidance states about the addressing of the misinformation of their products by the pharmaceutical companies on the Internet and social media platforms (Bennett et al. , 2014).

FDA in January 2014 drafted the guidance which provides pharmaceutical drug and biologics manufacturers with the FDA's current thinking on how to fulfill their post-marketing regulatory requirements for submission of "interactive promotional media" as it relates to their FDA-approved products (Gitterman , 2014). "Interactive promotional media" means technology that permits real-time communication and interaction with users which pharmaceutical drug manufacturers use to promote their products (Sarasohn-Kahn, 2008). According to the Guidance, examples of interactive promotional media include blogs, micro blogs, social networking sites, online communities and live podcasts. The Guidance provides pharmaceutical drug manufacturers with direction about whether they should report product communications that utilize interactive technologies to the FDA to fulfill their post-marketing submission requirements (Ventola, 2014). It also addresses the practical considerations that these manufacturers face with regard to submitting real-time information that is constantly increasing in volume and changing as it is posted online and shared by users.

In the U.S., post marketing surveillance of drugs occurs actively and passively. Methods to accomplish this include Phase IV clinical trials, in addition to voluntary and mandatory reporting through the FDA's Adverse Event Reporting System (FAERS), MedWatch, and the Institute of Safe Medication Practices Medication Error Reporting System (MERP) (Karimi et al., 2015). The MedWatch program, for example, allows the public (patients and providers) to report ADRs which they suspect or observe. While it is mandatory for manufacturers to report adverse events, reporting by healthcare professionals and the public is voluntary. Due to the voluntary nature of these systems, reporting and detection of adverse events may not be timely and is incomplete. Recent research has exposed the various inadequacies of spontaneous reporting systems, prompting researchers to explore additional sources for ADR monitoring (Chen et al., 2014).

The outcome of these regulatory guidelines will surely provide the benefit of using social media as a way of reporting of the ADRs and implementing this medium as a practice for the Pharmacovigilance for the companies.

Drawbacks for Social Media as a tool for Pharmacovigilance:

Rare adverse drug reactions (ADRs) may not be reported due to the limited amount of patients participating in such trials and the relatively short period of time these trials cover (Corrigan, 2002).

Hypersensitivity reactions or other patient specific reactions can be still unknown at the moment a medicinal product is marketed. Women, children, elderly and high-risk patients are usually excluded

from pre-marketing testing phase (Carnovale et al., 2016).

Traditionally, post-marketing surveillance or pharmacovigilance activities depend highly on spontaneous reporting systems (SRSs) for ADRs reported by health care professionals to the regulatory authorities. However, information obtained from analyzing SRSs is also limited due several reasons such as under-reporting by health care professionals, lack of sufficient clinical data, reporting bias and longtime latency (Poluzzi et al., 2012).

Current Status of Social Media in PV

Companies depend on various mediums such as email correspondences, company websites and physician hotline resources for reporting of AE. Today, more and more medical and consumer health companies are realizing the importance of having appropriate and sufficient controls over social media sites to avoid potential risks in the areas of reporting, identification and monitoring of AE data. Companies are now actively engaged to identify and understand the key factors for adopting a comprehensive PV social media strategy, which encompasses proactively creating social media platforms to capture AE data to enable an organization's social media monitoring and reporting activities as they relate to AE compliance and further examine the successes and challenges of the different types of social media platforms being used. Companies are now also providing their employees with social media guidance and best practices to facilitate effective safety reporting via social media. Employees are encouraged to be an active reporter for reporting safety issues/adverse events that they come across on social media sites, wherein side-effects are mentioned after having taken one of the client products drugs in a credible and identifiable way.

Thus, in the near future social media can be great tool for monitoring of the adverse events instantly and a great platform for consumers and companies to discuss their opinions and experiences regarding the use of the medicinal product or the device.

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