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Pharmacovigilance in the Digital Media Era

by Anastasia Marouda

Pharmacovigilance activities from the public sector or in the pharma industry have a very low awareness in the general population. Under-reporting is a common phenomenon in all countries. Efforts to improve this issue do not seem to have desirable results, because its extent has not been measured in accuracy. Even in countries with the highest reporting ICSR rates the reported proportion of serious reactions may not be more than 10% of the total occurring ICSRs [1]. Under-reporting is the main reason for delayed signals and can lead to an underestimation of the size of a problem. A signal suggests a new potentially causal association or a new aspect of a known association of events to medicinal products. However, in signal detection not only the quantity but also the relevance of case reports and the quality of data are important[2].

There are various reasons that have been identified for under-reporting; healthcare professionals may be reluctant to report adverse reactions in fear of putting them at risk of litigation or because it might reflect negatively on their competence; other reporters have doubts regarding the definite causality of the reactions to a specific medication and therefore do not report even though the legislation does not require reporting only if in these circumstances.

One possible solution to under-reporting seems to be the surveillance of digital media in order to collect more information related to pharmacovigilance. The widespread use of the Internet and of social media in particular has had a dramatic effect on the surveillance of drug use and related events[3]. Thirty one percent (31%) of the world's population are users of social media versus the forty six percent (46%) of the European population[4]. Millions of people can express their experiences from a specific treatment and this information is available publicly.

Patients reporting ADRs directly

It is evident from the statistics given by the European Medicines Agency (EMA) that patients are taking center stage in reporting adverse events to the authorities and MAHs. In 2016, 1,238,178 reports related to suspected adverse reactions were collected and managed in EudraVigilance, 339,544 of which originate from the EEA.

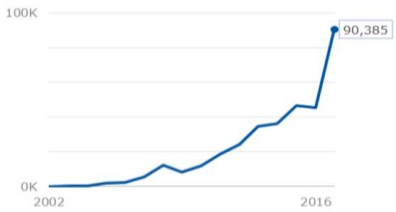

Figure 3. Trend of ADR reports received by European patients and consumers through the NCAs and MAHs.

Figure taken from 2017 Annual Report on EudraVigilance for the European Parliament, the Council and the Commission.

Health information is the most searched topic on the web. Statistics show that there are 7,4 billion Google searches on health-related issues on a daily basis. Furthermore, seventy two percent (72%) of internet users say they looked online for health information within the past year[5]. Moreover, research shows that twenty-

four percent (24%) of internet users, or eighteen percent (18%) of adults, have consulted online reviews of particular drugs or medical treatments[6].

This interest in health information from the public is also confirmed by the increasing number of Health applications that are available for downloading in smartphones and at they are estimated at approximately 195 thousand apps.

Big Data Enabling Better Pharmacovigilance

The pharmaceutical sector is experiencing a significant increase in the abundance of data which is currently made available by all sources of information such as clinical trials, pharmacogenomics and proteomics, computerization of health records, patient support programs and market research surveys as well as information from the media (ex. Social media). This enormous set of information is called "Big Data" and is of great value to the pharmaceutical companies and can make a difference in the outcome of a product lifecycle.

Big Data Analytics can be the foundation for pharmacovigilance for integrating and analyzing the all the available information in real time especially information which may reveal safety concerns. Safety concerns can have serious implications on public health and on a company's reputation and future.

With the increase in social media users and content and the constant increase in knowledge from research data sources are only increasing today and will only continue to increase at a faster rate.

So how do we handle digital media surveillance for Pharmacovigilance?

It has been previously recorded in literature that surveilling social media of ADR reporting has its advantages but also its challenges. Monitoring large amounts of social media data may potentially reveal new safety information about the use of medicinal products in daily practice. Especially, it might be a useful source for detecting safety information that is very rare and might not be detected before during the clinical trials.

However, the challenges that remain are significant. The quality of the data reported by patients is usually not the desired and also the verbatim used can often be inaccurate or misleading.

Furthermore, the validity of the reports is a challenge for the pharma industry. The new GVP VI module (Rev 2 Jul 2017) states that *"In relation to cases from the internet or digital media, the identifiability of the reporter refers to the possibility of verification of the existence of a real person based on the information available e.g. an email address under a valid format has been provided".* Reports from users with nicknames where it is not possible to perform follow to verify or identify a specific reporter could therefore be considered non-valid and thus limit the reports for further analysis[7].

From the Regulator's side there have been efforts made to create applications in order to facilitate the reporting of ADRs. For the European Union "WEB-RADR" has been created whose goals are to create a mobile phone application for the reporting of suspected ADRs to EU regulators, as well as creating technical tools for data mining publicly available data shared on social

media. These tools are still in pilot phase and have not been validated yet[8].

For the United States of America another application with similar logic has been created by the name of "MedWatcher". MedWatcher is a free mobile app and web app that allows users to learn about side effects of drugs, medical devices, and vaccines and to easily report adverse events to the FDA. MedWatcher strives to increase transparency around medical products and to improve the safety profile of drugs, devices and vaccines[9].

Both these efforts are in their very beginning and we cannot know if they will indeed provide a source of valuable safety data. For the time being it is definite that many man hours are being spent on behalf of the pharma industry in order to monitor social and digital media that is mainly under its responsibility, meanwhile possibly missing a vast amount of adverse event reports that are "dotted" around the millions of websites.

According the Good Vigilance Practice VI [10], official social media accounts of Marketing Authorisation Holders should be monitored continuously in order to comply with regulations on expedited reporting.

Currently Zeincro offers services and guarantees, 24/7 monitoring of all types of social media accounts, regarding reports safety information, on behalf of Pharmaceutical Companies and has already undertaken this service for a multinational company, regarding several of the affiliate social media accounts in European Countries.

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