

## BACKGROUND

Revolution within the health regulatory bodies since the disaster of the thalidomide related birth defects during 1961 has led the pharmaceutical companies to develop sophisticated measures to monitor the safe use of marketed products. Regulatory requirements have also changed from purely passive monitoring and reacting to alerts to a proactive approach that includes risk management plans and risk minimization, and from reporting only by healthcare professionals to patient reporting and exploration of social media and other social networks.

## OBJECTIVES

While some procedures and guidelines exist for the company sponsored sites, the strength of the pharmacovigilance data getting available from the non-sponsored sites is growing and hence there is a growing need to develop strong and much clearer guidelines to monitor the pharmacovigilance data from the websites.

## METHOD

A search on MEDLINE, Pubmed, CINAHL plus Full Text, Academic Search Complete, Alt Health Watch, Health Source, Google scholar and Web of Knowledge was conducted for studies published up to 2013. A search was also conducted on the available international guidelines for the monitoring of the pharmacovigilance activities.

## KEY CHALLENGES

The key challenges for a pharmaceutical company is to obtain the four information to validate an AE report.

- A contactable reporter
- An identifiable patient
- A suspect drug
- An adverse event

## REFERENCES

1. Knezevic MZ, Bivolarevic IC, Peric TS, et al. Using Facebook to increase spontaneous reporting of adverse drug reactions. *Drug Saf* 2011; 34 (4): 351-2
2. Keyuan Jiang, et al Mining Twitter Data for Potential Drug Effects
3. M. Abou Taam et al. Websites and withdrawal of benfluorex *Journal of Clinical Pharmacy and Therapeutics*, 2014, 39, 53–55
4. McGregor F Social media use by patients with glaucoma: what can we learn? *Ophthalmic Physiol Opt.* 2014 Jan;34(1):46-52
5. Hanson CL, et al., Tweaking and tweeting: exploring Twitter for nonmedical use of a psychostimulant drug (Adderall) among college students.
6. Yang C et al., Detecting Signals of Adverse Drug Reactions from Health Consumer Contributed Content in Social Media. SHB '12 Proceedings of the 2012 international workshop on Smart health and wellbeing. Pages 33-40.
7. Baron S, Goutard F, Nguon K, Tarantola A. Use of a text message-based pharmacovigilance tool in Cambodia: pilot study. *J Med Internet Res.* 2013 Apr 16;15(4)

## CONCLUSION

In conclusion, for pharmaceutical companies monitoring the social media discussion can be a challenging task however the potential rewards could be powerful with a better understanding of consumer usage. Recent years have seen an explosion in the use of social media and it is true that social media websites are going to stay. While the FDA is currently working to develop guidelines on social media websites an interim measure to monitor the adverse event reporting from the social media websites is urgently needed.

## RESULTS

We have assessed 7 articles where the authors have reviewed comments posted on the Facebook and Twitter websites. We have analysed the consumer's perception and the extent of the validity of such adverse event reports based on the FDA's four criteria.

### Published articles

- KnezevicMZ et al., According to the authors none of the adverse reaction reports were regarded as implausible and for much of the social media there is no intent to obtain or channel pharmacovigilance information to pharmacovigilance professionals – the information is simply there, floating in the ether! (1)
- Jiang K et al., The authors were able to demonstrate the validity of extracting data from Twitter posts and its ability to correctly extract potential drug effects. It is conceivable that social media data can serve to complement and/or supplement traditional time-consuming and costly surveillance methods (2)
- Taam MA et al., The authors concluded that analysis of website data can inform on drug ADRs. Social media are important for communicating information on drug ADRs and for assessing consumer behaviour and their risk perception (3)
- McGregor et al., Online forums give patients a space to air questions, grievances, suggestions and to provide mutual support. The information they contain may be of use to physicians by flagging adverse drug reactions, areas for service improvement or topics about which patients require more information (4)
- Hanson CL et al., Using twitter for the Adderall discussion, the authors were able to identify the normative behaviour regarding its abuse (5)
- Yang C et al., The authors were successful in detecting signals of adverse drug reactions from content in Social Media contributed by health consumers. The technique was validated when findings were tested against the FDA alerts (6)
- Baron S et al., The authors in this report concluded that using an SMS-based text message system were useful tools for practicing pharmacovigilance activities and that such tools can also be particularly useful for notification by patients or health users in an urban setting (7)

### Published Guidelines

- FDA's social media recommendations 2014
- “Firms are responsible for product promotional communications on sites that are owned, controlled, created, influenced, or operated by, or on behalf of, the firm” (eg Twitter, social networking sites such as Facebook) and the firm's blogs.
  - “Under certain circumstances, firms are responsible for promotion on third-party sites”.
  - “A firm is responsible for the content generated by an employee or agent who is acting on behalf of the firm to promote the firm's product”.
- GVP Module VI
- Marketing authorisation holders should regularly screen internet or digital media under their management or responsibility, for potential reports of suspected adverse reactions. In this aspect, digital media is considered to be company sponsored if it is owned, paid for and/or controlled by the marketing authorisation holder.
  - Unsolicited cases of suspected adverse reactions from the internet or digital media should be handled as spontaneous reports. The same reporting time frames as for spontaneous reports should be applied .
- CIOMS Working Group V
- A procedure should be in place to ensure daily screening by a designated person(s) of the website(s) in order to identify potential safety case reports.

Our result suggests that the benefit of social media to the pharmaceutical companies will not overwhelm the existing AE reporting networks. Moreover our analysis also suggests that the pharmaceutical manufacturers must look to compile a guideline that specifically covers the content of online discussion in a way that is different from the traditional way of reporting adverse events.

## RECOMMENDATION

1. People are more comfortable in online discussion and hence AE originating from Social media websites must be considered with similar value as the traditional way of reporting AEs.
2. The Pharmaceutical companies must build rules on how the employees engage themselves on social networking websites.
3. For users to join a company-sponsored social media site, appropriate permissions and disclaimers should be presented in advance in the terms and conditions. There should also be a mechanism to capture the AE through such sites.
4. Where a third party vendor is involved the PV obligation must be clearly agreed between the parties.