

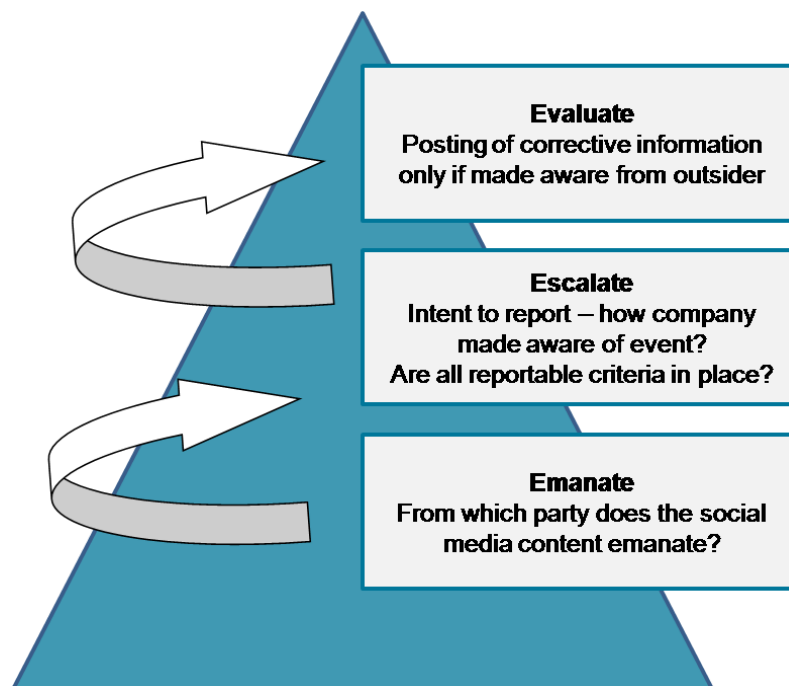
# Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools: Adverse Event Considerations

The world of internet promotion and social media has specific implications for adverse event reporting. WCI Consulting Limited is in a unique position to understand these implications because of our role as host to the **pvnet™** and **pvconnect™** network of 47 member pharmaceutical companies. Specifically, the **pvnet™** and **pvconnect™** membership comprise the Global Pharmacovigilance Heads from leading pharmaceutical companies.

The proposed framework within this response paper stems from WCI's deep experience in pharmacovigilance and, specifically, from working with a number of the membership companies on assessing social media concerns. This proposed framework assesses the implications of social media monitoring policies while also taking into account the intentionality of adverse event monitoring and reporting as well as industry drivers for social awareness.

## Executive Summary

Evaluation of adverse events which originate from social media should be evaluated in accordance with the following tiered '3E' framework for evaluation of adverse events which originate from social media:



This framework addresses the key questions posed by FDA with regard to social media, namely by identifying and presenting a solution for the key challenges and uncertainties that pharmaceutical companies face as they balance the need to provide timely and accurate safety profiles of products with the infinite amount of information dissemination that occurs via social media channels.



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## **Emanate: Role of Drug Company in Propagating Social Media Drug Content**

The baseline criteria for social media evaluation is the source from which the information emanates. We propose that companies have an obligation to monitor social media sites for adverse events if they 1) create the content on the site, 2) create the intellectual capital or vision behind the social media site, even if they party with a third party to develop and execute the site, or 3) financially pay for content on a social media site.

In this manner, companies can execute good pharmacovigilance principles by monitoring information which they generate for the public domain.

Industry strongly urges the FDA to accept results of social media monitoring aided by specific technological solutions that monitor and categorize website traffic.

## **Escalate: Further Evaluation Criteria for Adverse Event Monitoring Obligations**

The secondary criteria for social media evaluation is the escalation of that evaluation to include reporting intentionality. We propose that the consumer's intent to report should be a primary consideration in monitoring social media sites. In this manner, companies can provide a clear form with instructions on how to report an adverse event on any discussion board or website sponsored by a company. Should a consumer submit an adverse event in this manner, it is clear and apparent that the consumer is reporting a clear safety concern.

In addition, the impact of spurious reports on vital pharmacovigilance practices such as signal detection or aggregate reporting cannot be underestimated. Accurate safety profiles of products depend on the quality of safety information received as well as the quantity. If this vital safety data is diluted with reports where the consumer *may have a variety of motives for the communication* other than to report a safety concern (as is often the case with social media communication), the efficacy of signal detection practices could be weakened. To resolve this problem, it is key that companies be required to rely upon willfully reported consumer adverse events as much as possible rather than those uncovered by monitoring.

In addition, the forum membership proposes that regulatory authorities adopt a clear approach to define 'identifiable patient' and 'identifiable reporter' as part of the four minimum reportable criteria with regard to social media. For example, should email addresses or usernames be considered identifiable, and how can this be confirmed?

## **Evaluate: Role of Company to Perform Proactive Monitoring of Social Media Sites**

Finally, the third phase of evaluation for social media generated adverse events suggests that companies should be required to post corrective safety information if they uncover false information *as part of AE monitoring efforts*.



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Companies should not be required to proactively search the internet for false information regarding product usage.

In addition, if a company does post corrective safety information on a third-party site, that site should not be considered 'in the control' of the company – meaning that the company would not be required to continually monitor the site after posting the corrective information.

## Conclusions

The regulations which the FDA will effect with regard to social media will have far-reaching implications for drug safety and the safety profiling of pharmaceutical products to safeguard the public health. As such, companies should be encouraged to monitor content which they produce, control, or finance for impact upon public health.

Similarly, companies should be encouraged to focus on strong pharmacovigilance and safeguard the public health by carefully evaluating information that is willfully submitted to them, rather than devoting resource and time to monitoring the whole of social media for non-demonstrable impact upon actual new product safety information or profiles.