

UK ABPI – WHITE PAPER FROM ABPI PHARMACOVIGILANCE EXPERT NETWORK, DATED 13TH JUNE, 2011

The UK Association of the British Pharmaceutical Industry (ABPI) acting through its pharmacovigilance expert network (ABPI PEN) has published a white paper stating its belief that current European pharmacovigilance (PV) laws are not well suited to digital communications. The ABPI is looking to contribute to the updating of European guidance on good PV practices, which is due to be published in July 2012.

Pharmaceutical company-sponsored websites have been able to provide safety information and help the process of pharmacovigilance. Such sponsored sites can provide tools for reporting suspected adverse drug reactions, or enable a company to identify and contact a user to validate and follow up a report.

However, there is also a need to examine the role of social media in PV reporting in addition to the role of sponsored websites.

The UK ABPI acting through its disciplinary body the Prescription Medicines Code of Practice Authority (PMCPA) issued guidance on the use of digital communications by the UK pharma industry on 1st April, 2011. New European laws on PV have allowed for increased patient/consumer participation in the PV process, and the company-sponsored websites described above are useful here. ABPI PEN believes that the obligations on companies to monitor such company-sponsored websites for such PV reporting should be proportionate. Regulators may need to receive evidence from the industry that a risk-based approach to monitoring of such websites will need to apply, and all stakeholders need to devise such a risk-based approach.

However, PV data generated from non-pharmaceutical company sponsored websites is different from such data generated from pharmaceutical company sponsored websites. This may be because of (1) difficulty in validating or following-up with a reporter, or (2) a report arises unintentionally from “chatter” where there is no intention to report a suspected adverse drug reaction, and (3) CIOMS V (guidelines from a WHO/UNESCO body) suggests no obligation to report such events from a secondary care database because the information does not arise from a defined project such as a clinical trial and because the reports can be produced in duplicate by multiple individuals for various reasons and uses.

Therefore a pragmatic approach must be taken when dealing with PV data generated from non-pharmaceutical company sponsored websites. ABPI PEN proposes that pharmaceutical companies should not have a routine obligation to collect and follow-up on individual adverse events arising from non-pharmaceutical company sponsored websites. It is proposed that such data be treated as supporting data received from conventional sources and pharmaceutical companies and regulators need to work together to analyse such data so that it confirms or helps to generate potential signals. The approach desired by ABPI PEN is that the analytical method be tailored to the medicinal product and data, and not laid down by law. ABPI PEN proposes that a company should set out its approach in dealing with such PV data generated from non-pharmaceutical company sponsored websites in a document to be produced by the company in a PV inspection or through a PV risk management plan.

Social media can provide high volumes of PV data at high speed so can allow a company to see how its medicinal products are being used, soon after launch. Social media should also be used as a way of measuring the effectiveness of risk minimization activities.