

Drug marketing techniques may be risking patient safety

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With new drugs being reviewed by regulatory agencies and then released onto the market faster than ever before, patients' safety is being compromised, warns a study published on bmj.com today.

Dr David Kao from the University of Colorado Health Sciences Center, argues that while drug regulatory bodies are under pressure to make new drugs available more quickly, there are concerns that the deadlines for approving drugs have shifted the focus away from safety.

Kao reviews trends in drug approval times in the United States, and suggests how drug marketing techniques could be used to improve the way new drugs are monitored.

Previous research has shown that drugs approved in the US during the two months before the mandated deadline were more likely to be withdrawn for safety reasons or to carry a warning.

Today's marketing techniques are so sophisticated, says Kao, that once a drug has been approved the products can be released on websites within 90 minutes. He cites the example of Merck's new treatment (sitagliptin) for hyperglycaemia (high blood sugar levels)—within 14 days of approval 188 million patients or 73% of the insured US population had been targeted by the marketing campaign.

The danger with so many people trying a new drug very quickly, argues Kao, is that it can expose large numbers of patients to unknown risks.

When Merck's anti-inflammatory drug Vioxx (rofecoxib) was withdrawn from the market for safety reasons it had been available for five years and 20 million patients had been exposed to it.

Regulatory agencies have been criticised for their dependence on drug companies for funding. The agencies often collect fees from drug companies so that they can hire staff to review the drugs more quickly. The European Agency for the Evaluation of Medicinal Products receives 75% of its funding in this way, 43% of the US Food and Drug Administration (FDA) budget is similarly derived, and the UK's Medicines and Healthcare Products Regulatory Agency is completely funded by drug companies.

The author believes that the systems for reporting adverse drug reactions must be improved and suggests using the very same effective drug marketing techniques to do this. For example, laws in the US already compel TV adverts to instruct patients experiencing negative side effects to report their symptoms to the FDA. This could be expanded to include campaigns dedicated to drug safety monitoring.

Kao concludes by saying that the only drug monitoring system that will minimise unknown risks must involve all the key players in healthcare, including doctors, regulatory bodies, drug companies and patients.

Source: British Medical Journal

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