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Public Perceptions of the Pharmaceutical Industry and Drug Safety

Implications for the Pharmacovigilance Professional and the Culture of Safety

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Abstract

A survey of the US public titled 'Consumer Perceptions on Drug Safety' was conducted in October 2006. The survey was undertaken at that time because of the heightened public awareness of drug safety concerns over rofecoxib (Vioxx®) and pediatric antidepressant use. The survey was designed with questions related to public perception of the pharmaceutical industry, the US FDA, Congress and whether the US public perceived there to be a safety crisis. The survey consisted of 1726 US men and women aged 18 years and over.

The survey results showed that the FDA, Congress and US pharmaceutical companies are perceived as having a notable amount of responsibility to ensure safety (by 75%, 41% and 70% of respondents, respectively). Additionally, 96% of the survey respondents indicated that they had some level of concern about adverse reactions to prescription drugs that are taken as directed. Seventy-six percent of the respondents were 'fairly' to 'extremely' concerned about adverse reactions, while approximately 42% of the survey respondents' opinions ranged from 'somewhat distrusting' to 'strongly distrusting' of the pharmaceutical companies that develop drugs. These findings are comparable to those in surveys conducted by the Kaiser Family Foundation in 2005 and PriceWaterhouseCoopers in 2007. These surveys suggest that about half the respondents believe there is both the need and desire for reform in drug safety by the pharmaceutical industry and the FDA.

In reports from 2006 and 2007, the Institute of Medicine challenges the healthcare system and the FDA to adopt the principles of the culture of safety. While there have been steps taken to address the recommendations of the reports, as exemplified by the FDA Amendment Act of 2007 and the Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium, true reform across the life sciences sector will only come through broad adoption of these principles. Thus, it is particularly important for individuals and healthcare providers to track and report safety-related events involving approved and unapproved indications and medication errors. Pharmacovigilance professionals provide the foundation upon which the principles of the culture of safety can be built.

September and October 2004 were notable months for consumers of pharmaceutical products in the US. On September 27, the US FDA was informed by Merck & Co. Inc. that the Data Safety Monitoring Board for an ongoing long-term study of Vioxx® (rofecoxib), the APPROVe (Adenomatous Polyp Prevention on Vioxx) study, had recommended that the study be stopped early for safety reasons. This sudden announcement concerning rofecoxib was seen against the background of a hearing on 13 and 14 September, during which the Psychopharmacologic Drugs and Pediatric Advisory committees concluded with recommendations for a black-box warning on selective serotonin reuptake inhibitors about the increased risk of suicidal thoughts and behaviours, especially in pediatric patients.[1] A Congressional hearing followed on 23 September, during which the FDA was urged to take action on this matter.[2] On 15 October, the FDA issued a public health advisory on the increased risk of suicidality in children and adolescents being treated with antidepressant medications.[3] On 30 September, Merck and the FDA announced the withdrawal of rofecoxib.[4]

Consider also that during the first 6 months of 2004, the FDA issued 15 safety alerts or recalls for drugs, devices and over-the-counter medications,[5] and during the first 6 months of both 2005[6] and 2006[7] they issued 30 such notices.

There was clearly a focus on safety issues for the general public by the FDA, FDA Advisory Committees and Congress. And indeed, surveys conducted at that time and later have shown that the public had lost confidence in the pharmaceutical industry and the FDA.[8-11]

In addition, the FDA commissioned the Institute of Medicine (IOM) to examine in detail the system of drug safety in the US, the safety and efficacy of the drugs it reviews and, after their approval, their performance under real-life conditions. Real-life conditions include all uses; approved and unapproved indications and doses, as well as medication errors.

The variability in drug use and the interpretation of the findings is also a real-life concern for the pharmacovigilance professional. The challenge is to analyse and report frequently complex findings in a consistent and understandable manner for each stakeholder (i.e. prescribers, healthcare professionals, company officials, regulators, the financial community, patients and caregivers).

This is the background that led to the development of the consumer survey 'Consumer Perceptions on Drug Safety', conducted in October 2006 by Harris Interactive.[8] The survey population consisted of 1726 adults (aged 18 years and over) who were interviewed online, and was designed to represent the general public, with the exception of people who work in the healthcare industry or a regulatory agency or healthcare providers.

The research objectives for this study were to (i) measure the general public's attitude and perceptions regarding various drug safety issues; (ii) understand concerns regarding benefits and risks of prescription drugs among the general population; (iii) measure the level of US consumers' knowledge of the drug approval process and drug safety regulations; and (iv) identify key sources of health and drug safety information used by consumers.

The need for clear, understandable communication is a critical finding of Institute of Medicine reports[12,13] and PriceWaterhouse Coopers[9] and Harris Interactive surveys[8] conducted among the general public. This finding has a direct impact on pharmacovigilance professionals as they fulfill their professional duties. The pharmacovigilance professional is the foundation of the platform for reform called for in IOM reports where the culture of safety has been described.

Transparency and clear benefit/risk communication appropriate to the audience is a fundamental principle of the culture of safety, starting with the pharmacovigilance professional.

1. Measuring Consumer Confidence

What can be said about the level of trust that the public has of pharmaceutical companies as a source of therapeutic innovation?

The PriceWaterhouseCoopers study published in 2007,[9] reported that consumers had indeed lost confidence in the pharmaceutical industry.

The findings reported in the Harris Interactive survey reported in 2007,[8] and a Kaiser Health-Poll of 2005,[10] also suggested that the public had a substantial distrust of the pharmaceutical industry, where one-half of adults surveyed reported having an unfavourable opinion of pharmaceutical companies. In comparison, 77% of the survey respondents stated confidence in the FDA's ability to ensure the safety of prescription drugs in the US. Interestingly, 57% of respondents to the Harris Interactive survey[8] were only 'somewhat' or 'not at all' confident that companies would release safety information as soon as it was available to them. In addition, 56% were only 'somewhat' or 'not at all' confident that drug companies would eventually disseminate all information that they have, positive or negative, regarding the safety of their drugs. This finding supports one of the recommendations made by PriceWaterhouseCoopers[9] that the pharmaceutical industry should have increased transparency and provide complete and accurate information for consumers and stakeholders.

Aside from the high-level view of reputation, as determined in these surveys, how have attitudes changed in 2007 and 2008, and is there a persistent feeling of distrust or a safety crisis in the mind of the public?

While one should not make quantitative comparisons of any separate surveys, the qualitative findings of a range of surveys are consistent. A 2007 Consumer Reports[11] poll of 1026 adults found that the American public strongly backs a number of reforms. They report that nine of every ten Americans support reforms that would require warning labels and follow-up studies on drugs with safety problems, and public disclosure of all clinical drug trials. In addition, they reported that 84% of adults interviewed said the government should be able to 'take any action necessary' to ensure drug safety. More than 60% agree that both the FDA and Congress have failed to adequately protect consumers from harmful prescription drugs.

These findings are consistent with the 2007 Prescription Drug Safety National Survey[14] reporting that most Americans (64%) believe the US healthcare system is 'broken'. The survey also found that 46% of adults currently taking prescription medications report they are only 'fairly confident', 'somewhat confident' or 'not at all confident' that their prescribed medications are safe.

As stated above, these surveys, even when considering different methods and populations, provide the message that there is a serious concern over the safety of prescription medications, the pharmaceutical industry, and the review and approval process.

These findings are a concern for the pharmacovigilance professional because they call into question the very core of their professional activities. It is important for the pharmacovigilance profession to take a leadership position on the systematic reform required to address these important issues. One clear example of this leadership is in the form of support for the culture of safety, as reported in recommendations from the IOM.[12]

2. Towards an Agenda for Change

Any agenda for change by the pharmacovigilance professional is rooted in an understanding of the culture of safety and the implications for the entire life sciences sector.

The international risk management expert Ragnar Löfstedt points out that an erosion of trust in industry and legislators has been constant since the 1980s, due in large part to the ''sheer number and size of regulatory scandals''.[15] In addition to the IOM in the US, a recent assessment of pharmacovigilance by the European Commission found significant weaknesses in the current system of pharmacovigilance.[16]

In response to the findings in the US and Europe, important initiatives have commenced to improve the safety system. The European Medicines Agency recently announced that the PROTECT project (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium)[17] has been accepted for funding by the Innovative Medicines Initiative Joint Undertaking (IMI JU). PROTECT is a collaborative European project aimed at developing innovative methods in pharmacoepidemiology and pharmacovigilance. In the US, the FDA Amendment Act of 2007[18] provides the

foundation and funding for a number of important initiatives to improve the US safety system.

It is incumbent for all pharmacovigilance professionals to take an active role in these initiatives and even expand safety reform beyond the important steps that have been initiated from the European and US regulatory agencies.

Reforming the safety system as a whole and using a safety culture perspective is important as it emphasizes systemic means of dealing with reform, i.e. not focusing on single products or even classes of products, but rather on the underlying research and development and marketing processes, especially their safety-related intersections and potential gaps.

Pharmacovigilance professionals should help their organization to truly understand the broader implications of safety, and encourage clear communication between those responsible for developing and marketing pharmaceutical products; 'silo behaviour', where there is poor communication between groups within an organization, is clearly against the principles of a safety culture.

Active assessment of one's organization also means making constructive recommendations. As the basis for doing so, a fundamental self-assessment question is in order, asking "as a pharmacovigilance professional, how satisfied are you with how your organization communicates safety information to consumers and healthcare providers?" The leadership role of pharmacovigilance professionals in their organization includes promoting effective communication to each key stakeholder. Part of demonstrating this leadership is to consider the sometimes very subtle implications of human factors when setting up systems to support marketed products. For example, when reporting safety information, it is easy to assure consumer or healthcare professionals that it is easy to access the information from multiple sources and not just websites.

Understanding the core elements of the culture of safety is not just the role of the pharmacovigilance professional alone. Rather, it provides the framework for change for individuals and organizations. In the words of the IOM Report "Patient safety can best be achieved through the adoption of a culture of safety – organizational commitment to continually seeking to improve safety. To achieve high levels of safety culture, senior management of health care organizations must devote sufficient attention to safety and also make sufficient resources available for quality improvement and safety teams."[13]

Gathering the necessary data and interpreting and communicating the benefit/risk profile of the therapeutic product are deeply dependent on a multi-functional approach by companies, healthcare organizations and individuals. Moreover, what has become dramatically apparent is that there is also a responsibility of the marketplace, including active involvement of the public and healthcare professionals, in reporting adverse events.

There is no adequate system-wide safety culture at work within each of the organizations collectively making up the life sciences sector, the implication therefore being that products are risky to an unnecessary extent and trust is jeopardized.

3. Conclusions

Reform of the fundamental safety system includes three essential dimensions. First, a 'safety culture throughout the entire health system' (from bench through to delivery) – where there is learning from near misses and adverse events but not a focus on blame – should be the goal of each corporate and organizational entity. Such an approach goes against the entrenched 'silo' mentality and emphasizes the positive message of responsibility, communication and continuous learning/quality improvement. The direction of legislation (for example, in the US, the FDA Amendment Act) appears to be encouraging in these directions. But the real test of how entities adopt safety culture reform will be how it is integrated into their own transformations in response to both the global economic situation and the larger reformation of research, development, and marketing processes and procedures, requiring, as we have argued, a systemic approach itself.

Second, there must be continued efforts to bring together pertinent stakeholders in various collaborations to contribute to working within the legislative framework in order to create a positive environment to implement a safety culture

throughout the life sciences sector (embracing industry, payers, providers, advocacy groups and patients). The most effectively demonstrated of such mechanisms are public-private partnerships that are varied enough in range, formality and structure to provide the necessary flexibility to accommodate the vested interests of divergent stakeholders. The FDA Sentinel Network is an example of this type of program.[19] In addition, there is a particularly important role for individuals and healthcare providers to play (individually as well as participating in collaborative efforts) to track and report not only those adverse events related to potential and approved therapies but also those related to medication errors and off-label use.

Third, and as stated earlier, there are important initiatives underway in Europe and the US to improve safety. These initiatives challenge a cultural change in the leadership, professional participation and daily work of organizations involved in the life sciences sector. Just as how organizations should act safely to regain society's trust should be at the forefront of the pharmacovigilance professional's thinking and actions, how product and patient safety should be integrated into corporate social responsibility and governance should be equally high on the decision-making agenda.[20] This dimension of reform has to do with the knowledge as well as the conscience of leadership. It should span the spectrum of stakeholders, entailing executive decision-making imbued with a commitment to responsible public involvement, as well as balancing individual stakeholder vested interests with the greater good of public health.

In safety culture reform, the pharmacovigilance professional can and should have great influence.

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