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CURRENT OPINION

Empowering Consumers as Contributors for Health Product Safety: Lessons from the Philippines

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Abstract Empowering consumers to contribute to adverse drug reaction reporting seems a sensible innovation, particularly when traditional reports emanating from healthcare professionals are neither increasing nor improving. This work, inspired by an EU-FP7-funded project, describes an attempt by the Philippines to introduce a consumer reporting system through education and an online platform for reporting, and the lessons that were captured in the process. While participating consumers did not contribute to the adverse drug reporting process in the traditional sense as originally expected, the reports received by the drug regulatory agency revealed consumers' concerns regarding health product legitimacy, quality and market claims, as well as the lack of available and accessible information. These reports led regulators to take action. Initial insights on consumer behavior are proposed for regulators and industry to consider in greater depth and how this may impact on consumers providing valued information that will promote other aspects of product safety.

Key Points

Consumers and patients are important allies in ensuring the safety and efficacy of medicines.

Consumer reports may bring to the surface issues and concerns involving drug safety not previously covered in reports by health professionals.

Social media is a useful tool in increasing awareness and gathering information about pharmacovigilance.

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1 Introduction

An EU-FP7-supported project known as 'Monitoring Medicines' introduced innovation through its work packages 1–4. These work packages involved consumers directly participating in drug safety surveillance by strengthening consumer reporting [1]. That there should be no restrictions to drug-related harms that the public can report is considered quite relevant to the strengthening of the current pharmacovigilance system [2]. As consumers gain improved access to health technology and products due to more sophisticated direct-to-consumer marketing by industry, patients can be considered an integral part of a larger consumer-driven healthcare value network [3].

The current pharmacovigilance landscape in the Philippines has many challenges. Poor reporting by health professionals is a perennial problem. A celebrated libel case filed in 2010 by industry against a group of health professionals who reported adverse drug reactions (ADRs) contributes to a prevailing fear of reporting [4].

In terms of reporting rates, there is general sentiment that these are lower than expected for a current population of 100 million. Attempts to introduce pilot consumer drug reaction reporting between 2008 and 2010 were met with modest reporting outcomes, and led to the conclusion that improving public awareness was essential. At the time, the telephone was used as the method for contacting the regulatory agency, and reports were handled separately without much regulatory action or feedback provided [5].

2 Objective

This paper is part of a larger discussion of Monitoring Medicines initiatives meant to enhance patient contribution.

It briefly describes the current scenario of pharmacovigilance in the Philippines, and recounts recent activities initiated by the country's Food and Drug Administration (FDA) to involve consumers in the pharmacovigilance process, including gathering and analyzing consumer reports, taking regulatory actions, and analyzing lessons learned. One additional objective for the FDA to conduct this lay forum was to get a sense of consumers' issues with medicines.

3 Methodology

The Monitoring Medicines Project provided an opportunity to reintroduce a system for consumer awareness and participation for product vigilance reporting. A lay education forum and training workshop led by the Philippines FDA was undertaken in July 2013.

Grassroots advocacy was the main theme of the forum, described as a ground-up process wherein individuals, instead of the traditional leadership, initiate and conceptualize advocacy towards a goal. In brief, it was about consumer empowerment towards deciding on one's own health as well as contribution to health product vigilance.

1. A newspaper announcement and subsequent invitations were sent out through social media to various organizations, mainly consumer groups, local and multinational companies, schools and media organizations. Active solicitation was undertaken among organizations within the vicinity of the FDA office.
2. The education session, the advocacy awareness component, consisted of the following topics:

   ✔ Drug safety in clinics.
   ✔ Recognizing substandard medicines, counterfeit, smuggled or unregistered products.
   ✔ Recognizing products that appear to be making false claims, perhaps through intentional mislabelling.
   ✔ 'Patient Safety Always' as a concept involving long-term solutions such as public training, building networks, and seeking professional help.
   ✔ Recognizing the various clinical features that patients might encounter when taking medicine products.
   ✔ How to read product labels as a first step in safe medicine use.
   ✔ How pharmacovigilance units operate.
   ✔ The process by which a consumer can make a report, emphasizing salient details to complete a quality report for proper evaluation.
   ✔ How the FDA provides public assistance, and receives and evaluates complaints.
   ✔ Assurance that the FDA will take consumer reports seriously and act upon them.
3. A simplified online (e-ADR) notification process was introduced. This is a government-initiated and facilitative intervention, and can be found on the official FDA website (http://www.fda.gov.ph). Participants were also informed of social media platforms such as Facebook, which was utilized by the FDA as a way for consumers to articulate their observations and reports.
4. Advocacy materials such as posters, folders, pens and USB pen drives containing reading materials were given to participants with the request that they share the materials with their respective memberships and friends.

4 Results

A total of 151 participants came to the lay educational forum, representing a heterogeneous group from the community. There were teachers from a college health sciences department, representatives from patient groups and consumer organizations, including church groups, a few hospital representatives, a media columnist, and a small number of industry stakeholders.

After the talks and during the open forum with the participants, who interacted with the resource speakers actively, questions raised were assessed to be more clinical in nature, such as "Will prolonged use of nasal decongestants lead to hypertension?" Clarity was also sought on the long-term use of diethylstilbestrol and other hormones. Considering that these were coming from representatives of academia and consumer organizations, it would appear that they were not getting adequate critical product information from their healthcare professionals.

Other questions of note were about guarantee of confidentiality of reporting, the assurance of receipt of reports and how government feedback will be provided to them. Interestingly, many of the questions centred on their rights and privileges as consumers buying medicines from commercial drug retail outlets and how to access more drug information from the official government website.

After the July 2013 lay forum and workshop, and the introduction of the e-ADR notification facility, consumer reporting did not dramatically change; there were 29 reports (1.5 %) of a total combined reported adverse drug events (ADEs) [$n = 1880$] from various sources. There had been 28 consumer reports the previous year, representing 2 % of 1637 respondents.

As expected, reports were generally related to personal experience following intake of medicine products. Content analysis and evaluation of the few reports during internal agency discussions revealed that the quality of reporting and the level of detail were often insufficient to make an

Table 1 Examples of consumer reports to FDA Philippines 2012–2014 and actions taken

Concern	Date of issuance	Official advisories to the public
Between 2012 and 2013, unregistered stem cell procedures were being practiced and promoted at unaccredited health facilities. There were no scientific standards, and the procedures were being peddled expensively as a panacea to address all sorts of diseases	12 August 2013	FA 2013-023 Online consumer reporting on possible adverse events from human cells, tissues, and cellular- and tissue-based products (stem cells)
These were two different products which shared the same name. Confusion stemmed from marketing claims	15 August 2013	FA 2013-026 Arthrite Plus as food supplement and Arthrite SGC as traditional herbal product
The product came from an illegal manufacturer and was being sold with false and deceptive marketing claims	23 August 2013	FA 2013-030 Public warning on buying Citrange vitamin syrup being peddled in school premises
FDA postmarketing surveillance covers cosmetic products. Laboratory confirmation of these products showed the presence of toxic mercury	20 November 2013 and 8 September 2014	FA 2013-053 and FA 2013-053A Consumer warning against toxic mercury-laden skin whitening cosmetic products without notification that were tested by the FDA
This unregistered product was reported to have come from the southern islands, allegedly through illegal and unauthorized routes, and was being sold in non-conventional stores. The marketing claims were deceptive	15 January 2014 and 21 July 2014	FA 2014-006 and FA 2014-056 Public health warning (and reiteration) against the use of unregistered food supplement Sehat Badan

Source: http://www.fda.gov.ph advisories

assessment of causality. Therefore, these consumer adverse event notifications were considered inconclusive.

While participating consumers did not contribute to the adverse drug reporting process in the traditional sense as originally expected, the reports received by the drug regulatory agency revealed consumers' concerns regarding health product legitimacy, quality and market claims, as well as the lack of available and accessible information. These reports led regulators to take action (Table 1).

5 Discussion

5.1 Role of Government

It is one of the generally accepted roles of a regulator to make decisions that will protect patients and consumers from their inability to judge product quality and help them make informed choices [6]. Free flow of information is a requisite for success in pharmacovigilance work [7]. The alternative runs counter to cultivating society's trust in a public health agency. For instance, if a product defect is not investigated, with neither explanation nor action taken, the public may assume that the industry and regulators are in an inappropriate alliance.

The Philippines FDA attempted to create a transparent, user-friendly system for adverse event consumer reporting and invited the public to participate and engage in the regulatory process. Reports of adverse events, when taken seriously with appropriate evaluation and actions, will help in signal detection.

During the July 2013 workshop, participants claimed ease in using IT reporting, which was seen as a potential avenue for alternative reporting, particularly when healthcare professionals are unable to carry out the adverse event reporting. However, actual results were not supportive of this theory as low consumer reporting numbers were observed.

Interestingly, some of the reports were neither strictly related to pharmaceutical products nor ADEs but were associated with health technology, health supplements, vitamins or cosmetics. These reports contained questions on intervention and product legitimacy, quality, toxicity/safety and promotional claims. They revealed consumer concerns of a different nature which were nevertheless deemed important enough by the public to report to government authorities. These reflected the prevailing sentiments of the individuals who made the effort to tip off the Philippines FDA on what they were seeing in the market. These consumer reports were also picked up through the Philippines FDA either through the eReport or Facebook over the year, and led to a series of regulatory actions such as advisories (http://www.fda.gov.ph) and warning letters to errant trade entities, as well as product confiscation, if warranted.

In addition, through the use of social media tools such as Facebook, whistleblowers began to be willing to report questionable establishments, products and claims. This has also led to a number of regulatory investigations, some of

which were in fact found to be violative, for which actions were taken.

While social media can be a useful tool for disseminating information on drug safety, it has also been used to perpetrate misinformation. Internet online platforms have been used to sell pharmaceuticals and other healthcare products directly to the public, often accompanied by dubious therapeutic and marketing claims.

Within the year after the workshop, the Philippines FDA received reports of a number of cases wherein the public believed in false therapeutic claims of marketed health supplements. In order to protect the consumer and empower them to make rational informed choices, the FDA created a Health Scam Unit at the agency to focus proactively on capturing various false claims found in the media (newspaper, radio and Internet), with the end view of taking regulatory actions (advisories, warnings and product recalls). The Philippines FDA issued a number of public warning advisories as well as informing online platforms that such trade was considered illegal [8–11].

When science education is weak, people tend not to be skeptical or ask questions and can easily be misled. Any attempt to improve science and logic in education would be most welcome as this will be an investment in consumer empowerment.

Consumers are expected to report fake medicines, yet they may be unable to determine fake from real. How would the public know about industry compliance to current Good Manufacturing Practice (cGMP), and those using real from fake active pharmaceutical ingredients (API)? For the public to be made aware and consumers empowered, there is need for education.

In addition, consumers think that it is the responsibility of government to prevent the entry and spread of counterfeit drugs, and that industry should take responsibility for their products when harm develops. Because the pharmaceutical supply chain is too complex, the public puts its trust in regulators.

Government must establish a neutral platform for reporting because industry, particularly local companies, cannot be assumed to be monitoring product quality consistently and comprehensively. However, governments may not always have adequate resources to inspect, audit, test and prosecute wrongdoers [12].

5.2 Role of Industry

It is incumbent for the pharmaceutical industry to build drug safety into the entire cycle of producing and marketing medicines. Given the complexity of the pharmaceutical manufacturing process and the supply chain, it is often difficult to determine and ascertain the root causes of adverse events.

According to the law, when someone knowingly and willingly enters a dangerous situation, then sustains injury, that person is often barred from any recovery. Thus, patients who know the benefit-harm risk ratio of an untested medicine and who still decide to use it are in effect giving consent. In reality, the problem is this: based on observation from local clinical practice, doctors and patients hardly read and usually ignore the fine print of the product information. Industry includes a disclaimer, ‘use as indicated’, which effectively protects them. For example, when adverse events arise from off-label use of the medicine, the industry is absolved of responsibility, and the shared burden shifts to the prescriber and the patient. Interestingly, consumer personal injury that leads to establishment of claims often involves the pursuit of corporate wrongdoings [13].

Philippine consumers are not litigious by nature. Nevertheless, industry should take product liability issues seriously and should study this in the context of pharmacovigilance. Improper manufacturing of products may cause injury and may lead to negligence claims. Tort awards for defective products can bankrupt a business.

5.3 Role of Consumers

With patients inundated with market advertising in this digital age, it can be quite difficult to make sense of all the available information; hence, a partnership based on trust is needed with a clinical doctor who must keep abreast of ever-evolving scientific literature to be able to provide proper patient advice. While the attitude and perception toward risk vary from person to person, a high level of patient autonomy in healthcare decision making has come to be expected as the norm in modern medicine [14].

When given a choice, patients and consumers practice product brand loyalty. For medicines, this is largely decided by their healthcare professionals and affects overall patient compliance. Payment schemes for healthcare may also dictate the patient’s ability to report harm as they may feel beholden (e.g. in case there is a closed formulary during medical consultation and treatment) to a set of reimbursable products, or if no choice is provided or when a cheaper substitution is made at a dispensary. Given the uncertainty of healthcare, patients are less likely to demand and analyze cost-effective treatments [15].

There are factors that affect consumer involvement in product efficacy and harm. First, they have to suspect that an adverse event has occurred. They then need an easy way to transmit reports to a central repository—in this case the FDA. The third is to receive acknowledgement and feedback. Finally, consumer participation is reinforced by knowing that regulatory actions have been taken regarding their reports.

Consumer involvement signifies the perceived personal importance or interest that the person attaches to the buying, using and disposing of goods. As this involvement increases, the consumer has greater motivation to want more information about the purchase and about the product. Some of the factors that characterize this involvement include the following: when buying or using risky products, when the product is expensive, personality or stature of the product user, and situational, such as the context of the use of the product [16].

There are merits for consumer empowerment and reporting. It makes good sense to have consumers be part of the process for reporting ADEs as well as problems they encounter with products, to assist regulators to take appropriate safety actions. There are also local anecdotal reports emanating from patients that clinicians often ignore their adverse drug experiences. Information provided by doctors or pharmacists were not always sufficient for the patient. Patients do want to be taken seriously [17].

5.4 Potential Hindrances to Reporting

Reporting is a form of expressing discontent. A previous study on consumer behavior revealed that households will report a problem when they are dissatisfied; 22 % of reports were due to unsatisfactory product quality; therefore, industry can increase their value by increasing the satisfaction of consumers. Sometimes, consumers will tolerate product deficiency, which can be explained by adaptation theory. It was estimated that 60 % of dissatisfied consumers did nothing, partly because non-complainers seemed powerless and had less knowledge of means of redress [18]. However, these principles seem not to generally apply to medicinal products which may seriously impact on one's health. In the Philippines, it is unfortunate to note that current reporting rates are extremely low, even among consumers.

The following are possible reasons why consumer reporting in the Philippines may not be working as expected.

1. Ignorance and lack of information. Filipino patients are rarely provided medicine information in the clinics by their doctors or at the dispensary by pharmacists. Known adverse effects are not recognized. Recognizing that patients generally were not being provided critical information about their medications, the Philippines FDA issued a gentle reminder to health professionals, both physicians and pharmacists, to exert their professional obligations and diligently provide essential product information to patients/consumers [19].
2. Competing public health programs divert government focus from consumer awareness.
3. Waning consumer confidence in the sincerity of government intervention may lead to apprehensiveness to report. Consumers will stand up for their rights and boldly complain to obtain a replacement or a refund for other commercial products, but may not do so for medicine products.
4. Relative absence of altruism. Altruism is the most important factor for consumer reporting of ADR. Based on the study of Van Hunsel et al, the basis for consumer or patient reporting was one of looking after the welfare of others, preventing harm to other patients, making ADRs known, contributing to increasing knowledge, and to improve the product information leaflet. The motives for reporting included the severity of the ADR and the need to share their experiences. Some of these experiences generated anger. Patients articulated that they wanted more information about the adverse reaction, and wanted confirmation of their experience [20].
5. No sustained media interest. The influence of media attention and broadcast on an issue may affect public reporting. Notoriety bias has been explored previously [21]. The Philippines media hardly discusses the importance of pharmacovigilance or product concern, except when the Philippines FDA issues an advisory; even then, news coverage is usually short-lived.

5.5 Applying Business Models to Pharmacovigilance

Regulators and industry would both benefit from studying consumer behavior. The creation of a practical user-friendly reporting system benefits all stakeholders.

The rise of consumerism started in the 1960s, with advances in education and income, socioeconomic-ecological discontent, the changing complexity of marketing, which also leads to marketing discontent (subquality products, dishonest gimmickry and claims), the establishment of consumer organizations, bold mass-media coverage, and sometimes business and legislative indifference to the needs of consumers [22].

People and society are not merely beneficiaries of the health system but should also be viewed and invited as active participants in both developing and driving health systems improvement. The indispensable participation of individuals, civil society organizations and stakeholder networks can greatly influence and improve the building blocks of health systems—fairness, social justice, participation and collaboration [23].

Consumer empowerment is studied as a form of behavioral economics. How they make decisions follows a pattern and obeys rules, called alternative utility functions, which cover loss aversion, altruism, reciprocity, desire to

support others and ethical commitments. Pharmacovigilance as a discipline can study and understand this whole science of behavior economics and consumer empowerment [24].

There are some observed principles in behavioral and health economics. In healthcare, there is a concept known as physician-induced demand which follows the model of utility maximization. Because of information asymmetry, patients rely on their trust in their healthcare workers. However, physician decision making can be motivated or influenced by other factors outside of known scientific information (e.g. practice of local norm). Patients become vulnerable, especially when complete information is not provided. They place their trust in the healthcare system (consequently, to participate in product safety reporting becomes aspirational) and do not demand better services and products. Unfortunately, the market for healthcare is slowly evolving to become like other markets. There is a palpable shift in the doctor–patient relationship from one of trust to a mere economic transaction. This invariably affects the patient's view on using a medicine or on seeking a second opinion.

One example is a critical care setting with life-threatening conditions. People in such situations may exercise more care in examining available information prior to use. In the desire to benefit from the medicine in such dire situations, they may choose to downplay or tolerate the uncomfortable side effects of the medicine.

This situation allows us to reflect on how industry and regulators alike can apply business concepts and tools covering the sales of products (marketing communications) into an after-sales service (such as the reporting and capture of complaints so steps can be taken for the betterment of client services). Further studies may be needed to elucidate how to position the practice of pharmacovigilance into the daily lives of people and how to expose the public to more consumer empowerment.

One potential business tool is social marketing, which may be used as a strategy by a group of change agents, with the objective of persuading another group of target adopters to accept, modify or abandon ideas, attitudes, practices and behavior. In brief, social marketing is a technique applied to encourage behavior change for the better. For consumers to be effective contributors to health product safety, they have to be empowered and willing to adopt a system designed by government and industry to capture these reports [22]. However, the ecosystem for creating the culture for consumer reporting is far more complex than merely introducing awareness, education and a platform for reporting. There are divergent ideas, conflicting attitudes, and current behavior and practices that need to be altogether researched and addressed.

As we can see from the initial reporting by consumers, their concerns are much different from the initial intention of the project. Perhaps it is incumbent on government regulators and industry players to embrace social marketing concepts to be able to adopt the changing paradigms for product safety.

It is unlikely that one lay education forum would lead to some catalytic change in consumer and patient reporting. Moving forward, it makes sense to find innovative ways to sustain public interest in pharmacovigilance beyond regulators taking actions on consumer findings.

6 Conclusions

There may be a need to redefine traditional thinking on pharmacovigilance. Expanding pharmacovigilance to cover all risky situations may be an integrative step in improving consumer empowerment and the quality of reporting. These may also include online access to health products and food products. After all, the public's safety must take into consideration consumer exposure to all types of products, how they are marketed and sold, and where they come from.

Consumers and patients are important allies in ensuring the safety and efficacy of medicines. Consumer reports may bring to the surface issues and concerns involving drug safety not previously covered in reports by health professionals. They reveal genuine concerns for obtaining better information about the quality and efficacy of health products. Social media can be a useful tool in increasing awareness and gathering information about pharmacovigilance.

Furthermore, the initiative to get citizens of a low-income country to participate in reaction reporting has exposed the need to educate the public (awareness creation) and encourage the culture of reporting to extend beyond pharmaceutical products, whether the risks are perceived or real, and to question the quality, marketing claims, and legality of any product in the market.

Regulators or policymakers should not merely assume that consumers are aware of these, and that the reporting system is easy to use. To enhance the effects of such lay education fora, these can be designed to target the leadership of organizations covering larger geographical areas, and sustained by repetition and reinforcement.

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