

Prescriptions for Excellence in HEALTH CARE

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Safety Matters

By *Donald G. Therasse, MD*

In recent years, greater emphasis has been placed on patient safety and pharmacovigilance systems that aim to minimize the risks and maximize the benefits of pharmaceutical products for targeted patient populations. The result has been a revised approach to pharmaceutical risk management and risk communication, which provides an excellent opportunity for more effective interactions and increased transparency with regulators, health care providers (HCPs), and patients.

Increasingly, regulators are communicating potential serious risks to the public earlier in the evaluation process. Although some consumers, patients, and HCPs welcome this information, others find such messages confusing or misunderstand what the communications are intended to convey. These communications often lack broad context regarding benefit and risk, and are delivered in the absence of a clear explanation of how the safety surveillance system works.

The safety of patients using Lilly medicines is our highest priority.

Beginning with the discovery of a potential new drug, and for as long as it is available to patients, our goal at Lilly is to ensure that the benefits and risks of a medication are continuously monitored and well understood by regulators, HCPs, and patients. Even after thorough

research in clinical trials, Lilly continues to carefully monitor for new safety information, so safety evaluation does not stop when a medication reaches the market. In fact, the monitoring increases through collection of information from ongoing clinical studies and through reports received directly from the HCPs and patients who use the medicine. Lilly shares new findings and emerging concerns openly with regulators and HCPs to ensure appropriate management of the risks associated with the use of our medicines.

Safety Matters Web Site

Accurate and up-to-date safety information is critical for HCPs and patients to best decide how and for whom a medication should be used. Lilly recently launched a new section called Safety Matters (<http://safetymatters.lilly.com/>) on its Web site to provide HCPs with additional information on how Lilly monitors the safety of its products. Safety Matters also includes links to the US Food and Drug Administration (FDA) Web site and provides an explanation of the Global Patient Safety (GPS) organization within Lilly.

As part of the development of the Safety Matters Web site, Lilly conducted interviews with HCPs

and researched similar Web sites of other pharmaceutical companies. The interviews with HCPs showed that:

- Many are not aware of the FDA site as a resource for product safety information.
- They infrequently report adverse events.
- They are unaware of pharmacovigilance processes.
- They believe that only those adverse events that are unusual, unexpected, or serious are to be reported.

Safety Matters includes sections that highlight the safety-related roles of HCPs, Lilly, patients, and the FDA. It also includes links to prescribing information and medication guides for all Lilly medications, as well as links to a number of relevant FDA Web sites, including specific links and instructions about how to report an adverse event. A separate section explains the company's pharmacovigilance processes, which are designed to continuously monitor, evaluate, and communicate a drug's safety profile. The Safety Matters site currently focuses on a US audience, but plans call for it to be expanded globally.

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Lilly Global Patient Safety

The GPS organization is a team of over 300 individuals, including physicians, pharmacists, nurses, and other drug safety professionals, who have the core responsibility for pharmacovigilance and the continuous monitoring of the benefit/risk balance of Lilly's products. GPS continuously and actively monitors safety information from sources around the globe. When a safety finding is identified, the GPS team works with regulatory

authorities to inform HCPs and patients. This information is communicated through changes to the medication's package insert, patient information guide, and occasionally through letters sent directly to HCPs or by other means. When necessary, additional studies are conducted to further assess and understand the safety profile of the medication.

Lilly aims to model good risk communication practices through the Web site, and to create an

evidence-based communication tool that could be adopted by others who communicate risk information to the public. It is important for Lilly, regulators, HCPs, and patients to work together to ensure that all stakeholders understand their roles in patient safety and the pharmacovigilance process, and in the reporting of any potential adverse event that occurs during or after treatment with a medication.

Donald G. Therasse, MD, is Vice President of Global Patient Safety at Eli Lilly and Company.