Pharmacovigilance – Patient’s standpoint
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What is Pharmacovigilance?

Pharmacovigilance is defined as “the detection, evaluation, understanding and prevention of adverse drug reactions (ADRs)”.

The ultimate aim of pharmacovigilance is the optimization of the risk-benefit ratio of marketed drugs at the individual level (i.e. the choice of the most suitable treatment for a given patient) and at the population level (i.e. maintenance or removal of a drug from the market, informing prescribers of its potential risks, etc.).

The current pharmacovigilance approach is purely reactive and can only be as good as the ADRs being reported and communicated on a timely and reliable basis.
Why are we talking about this topic here?

You identified drug safety issues as fitting within your overall span of control as compliance professionals.

The majority of stakeholders to the industry view this topic as critical to restoring the industry’s failing reputation.

A likely next step is determining the compliance department’s role vs. that of the drug safety and other compliance audit functions.

Protecting and enhancing your company’s reputation should be a cornerstone of your compliance department’s mission statement.

PricewaterhouseCoopers
How to improve pharmacovigilance (stakeholder’s standpoint)?

What do your stakeholders think are the problems?

- 62 percent of stakeholders agreed that drug companies often manipulate or suppress negative clinical trial results to maximize sales. One in five pharmaceutical executives agreed.

- Only one half of consumers but three-quarters of industry executives agreed that drug companies have sufficient programs in place to monitor their products’ post-market safety profile and public health risks.

- More than half of Americans (55%) said that drug companies don’t fully communicate news concerning negative affects and dangers associated with their products.
How to improve pharmacovigilance (stakeholder’s standpoint)?

What are some potential solutions?

Foster a culture of compliance and patient-focused behavior. By ensuring that the company demonstrates dedication to ethical, patient-focused behavior and by implementing fundamental changes in the processes and tools that are relevant not only to the efficient and effective conduct of business operations but also to reputation management, pharmaceutical companies may guard against exposure to excessive and unnecessary business and financial risk—and thereby protect stakeholder value.

Educate the public. Communication on the benefits of the industry for the day-to-day lives of patients—as well as communication on the risks and costs inherent in the development of new drugs for future consumption—is needed if patients are to understand the role of the industry in their personal health cycle. An improved understanding of the role of the industry in enhancing personal lifestyle and longevity will reestablish the trust and the bonds that have historically existed between the patient and drug company.

Explain the broader benefits of the medicines the industry delivers. Improved communication of the broader socioeconomic benefits of modern drugs will enhance stakeholders’ esteem for the industry and help educate the public on the impact of modern drugs on healthcare in general. Improved understanding may make price justification easier in a market in which government pricing policies impede industry economics.
How to improve pharmacovigilance (from patient’s standpoint)?

**Timely communication**

Public information and education campaigns, through the EMEA and national agency websites, health centres and patient organisations, etc. on the importance of side effect reporting should be carried out and it should be a key part of training for health professionals.

Also, contacts between local pharmacovigilance and patients organisations to get feedback are to be planned. Internally, the EMEA should define a communication policy and discuss on when and how to communicate in order to improve the correct use of medicines.
How to improve pharmacovigilance (from patient’s standpoint)?

**Improve patient information leaflets**

Patient information leaflets need to be designed to convey potential adverse reactions more clearly, so that the relative likelihood of these occurring is included and people know what to do if they do occur.

**Introduce a symbol to indicate new medicines and increased surveillance**

Patient information leaflets and packs should carry a symbol if a medicine has been on the market for less than five years or is under intensive surveillance for any other reason.

Source: www.epha.org
How to improve pharmacovigilance (from patient’s standpoint)?

Proactive Pharmacovigilance

In organising an active follow up of adverse events after marketing, which would involve patients and carers as responsible players, possibly through well conducted prospective surveys for the medicines not yet widely known.

The EMEA should also establish direct from consumer reporting, as a pilot project, looking at lessons that can be learned from national schemes, such as in Denmark and The Netherlands, and also from the FDA in the U.S. Such a system could be set up through the introduction of a toll free number, a website for feedback or adding a reply form to the patient leaflet.
How to improve pharmacovigilance (from patient’s standpoint)?

**Improve transparency**

In providing better and more regular information, giving health professionals access to all information on the safety of medicines, so that they can speak frankly with their patients and make informed choices; by designing prioritised information leaflet for patients, to help them understand the most frequent and serious risks and how to avoid them.

Therefore, the EMEA pharmacovigilance database should be available to health professionals, consumer and other organisations with a legitimate interest in human health and patients.

Patients have the right to be informed about any potential side effect of a medicine on the market.

Source: www.epha.org