As a first step, adverse effect reports (AERs) must be translated from the local language to English, with particular care being taken to ensure that patient confidentiality is not breached at any point in the process. Eventually these reports, combined with additional documentation, are translated into a number of multiple languages to accommodate the requirements of various countries.

The Internet has a significant role to play in this important discipline. Since all concerned parties can obtain almost all information for any adverse event on the Internet, both regulating agencies and the public will be as informed as anyone in the industry. It is vital and in the public’s best health interest that adverse events reported are published on the Internet, and translated consistently into languages that are needed. Medical organizations, pharmaceutical and medical device firms, regulatory agencies and consumers are attuned to the need for accurate, accessible information to promote proper prescription of medical drugs and devices.

As a result, Good Pharmacovigilance Practice (GVP) is receiving much greater attention from all stakeholders. One of the challenges of implementing GVP is the management of complex communications that require a high degree of accuracy. Given the multilingual makeup of the parties reporting on and sharing this information, language transparency is of the utmost importance. Errors in the reporting or translation process can have an egregious

---

**Five keys to language transparency and optimized reporting**

**Pharmacovigilance, an arm of patient care with a charter to make the best use of medicines and data for the treatment or prevention of disease, is taking on growing importance in global public health. Pharmacovigilance is a multi- and cross-area discipline that deals with incidence and frequency of adverse events of pharmaceuticals and medical devices worldwide.**

The reporting of adverse events is critical to the creation of a valid pharmacovigilance program that can identify adverse events before they have an impact on public health. However, language can be a barrier in the reporting process. In many instances, adverse events and databases are reported in the local language.
effect on both patients and providers. Additionally, without the proper controls in place, language translation risks and costs can quickly escalate into many thousands of dollars for a pharmaceutical manufacturer or distributor. Language transparency and translation costs can be improved by laying the right foundation for multilingual communications. A number of best practices can be followed to reduce risk, increase the worldwide knowledge base, expedite reporting and control costs related to pharmacovigilance. Stakeholders can reduce their risk and streamline the translation process and costs by partnering with a qualified language services provider (LSP) that offers the right combination of expertise, infrastructure and resources to meet their needs, including:

1. Documented, internationally recognized quality and risk management standards
2. A high quality, documented methodology for qualifying and managing pharmacovigilant-centric resources
3. Web-based technology tools to foster efficiencies and process optimization
4. Client-dedicated teams for optimal process management
5. Responsive service to accommodate multiple geographic regions

Following is a more detailed discussion of the origins and evolution of pharmacovigilance and the impetus for establishing worldwide best practices in language translation and program implementation.

**ORIGIN OF PHARMACOVIGILANCE**

Pharmacovigilance is defined as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems” (World Health Organization).

The need for special pharmacovigilance rules and regulations arose as a result of adverse effects of pharmaceuticals and, to a certain extent, medical devices on patients. The thalidomide disaster, although not recent, represents one of the most important cases to highlight the need for pharmacovigilance and its impact on the future of drug development and legislation.

Thalidomide was not approved in the U.S. by the Food and Drug Administration (FDA) at the time that its adverse effects on pregnant women were discovered. Hence, almost all cases originated in Europe. Even so, the adverse effects were extensively reported on and led to stricter regulatory frameworks for the development of new drugs in the U.S.

Such risks relating to other drugs and medical devices still exist today, driving the need for preventive pharmacovigilance. For example, an existing pharmacovigilance program may have identified serious adverse events ahead of a major catastrophe in the clinical testing with immunological interventions (e.g. TGN1412,
an immunomodulatory humanized agonistic anti-CD28 monoclonal antibody).

Such a program may also have identified adverse effects related to the anti-obesity drug Redux in the U.S. that caused an over-representation of serious depression. It may have also identified the risks involving the anti-hyper intensive drug Selacryn, which increased mortality beyond normal levels in the targeted patient population, and of course lately, non-steroidal anti-inflammatory drugs.

Another classic example is the asthma inhaler containing isoproterenol, causing an epidemic rate of deaths among children in Great Britain, Australia and elsewhere. The cause of this reaction appeared to be an unusually high concentration of the compound in these inhalers.

This medical catastrophe as well as the thalidomide disaster points to a very important factor in drug development: the dose must be correctly adjusted for sex, age and often nationality (Gieringer, The Cato Journal 1985). That is another good reason why a pharmacovigilant program is part of public safety policies.

Today, pharmacovigilance is an arm of patient care that involves consumers, health care professionals, pharmaceutical companies, global regulatory agencies and media. It is a multi-area discipline with a goal to make the best use of medicines and data for the treatment or prevention of disease and all issues related to the safety of the public. Good Pharmacovigilance Practice (GVP) is receiving much greater attention from all the stakeholders in drug and device development. Pharmacovigilance has also created its own non-profit scientific organization, the International Society of Pharmacovigilance, which arranges annual scientific meetings where research in the field of pharmacovigilance is discussed.

THE ROLE OF PHARMACOVIGILANCE IN PUBLIC HEALTH AND SAFETY

The fundamental driving force of pharmacovigilance is the safeguarding of public health. The basic need for pharmacovigilance grew out of the clinical trial setting, because during the development of new drugs and devices,
many of the patients who will end up using the medication or the device are excluded from the trial. Therefore, for example, rare adverse events may not be identified until larger populations use them for a longer period of time. Public health programs need to:

• Quantify and characterize risks to individuals and communities from their medicines
• Minimize harm and improve use
• Sustain public confidence in the programs, and track problems due to medication errors and poor quality medicines

The pharmaceutical industry and medical device industry have an important role to play since they are usually at the center of adverse drug reporting.

In most cases, adverse drug reporting and adverse device reporting is the initial place where information from the patient is received, investigated and later relayed to the regulatory authorities. Real World Data (RWD), a form of pharmacovigilance data, is important to the pharmaceutical and device industry so they can inform on better therapies and much safer treatment options that will lead to better health outcomes.

Payors, health technology assessment organizations and regulatory agencies have also started to use RWD as part of their decision making process.

Significant harm to a few patients can destroy the credibility, adherence to, and success of a program or drug treatment. Rumors and myths about the adverse effects of medicines can spread rapidly and are difficult to refute in the absence of good data. Pharmacovigilance can provide such data.

Public safety actually demands these programs to be in place, and there are advocate organizations following the safety of compounds as well as physicians, and legislators who perform the same tasks.

With the advent of comparative effectiveness guidelines and regulations, at least in the U.S., safety of compounds will be included in these efforts to evaluate the safety of a compound long term. Interest groups are not limited to pharmaceutical industries, but also include insurance companies and other payors who are extremely interested and follow the outcomes closely.

Education and knowledge are vital factors in understanding adverse events, and when and how they should be reported. In a study of 108 physicians working in a teaching hospital, a general underreporting of adverse events was recorded.

The major reasons were an inadequate perception of risk for newly marketed drugs, the fear factor, insufficient training to identify the event, a poor understanding of the reporting regulations and forms, and not being interested in adverse events (Khan, SA et al.).
In many developing countries, language can be a barrier to public health pharmacovigilance reporting. To address this, coordinating centers and institutions must rely on a qualified Language Services Provider (LSP) to provide compliant, uniform reports that can be used worldwide.

One example of the importance of accurate information gathering from public use of medicine can be found in the country of Senegal, where malaria represents an endemic health risk. Early diagnosis and prompt treatment with an effective anti-malarial drug is a priority for the National Malaria Control Program (NMCP) in Senegal.

However, when this strategy was threatened by the spread of chloroquine resistance, the NMCP adopted artemisinin-based combination therapy (ACT) in line with WHO treatment guidelines. At the same time, Senegal’s health organizations identified the need for a more vigilant system for antimalarials and for ACT particularly as part of the introduction plan of these new drugs.

This brought together the competencies of the Ministry of Health, the National Centre of Pharmacovigilance, and other academic and private sectors and partners such as WHO, UNICEF, USAID and civil society organizations under the coordination of the NMCP to develop and implement a dedicated safety monitoring system of antimalarial drugs in all the public health services in Senegal in 2007. Senegal’s pharmacovigilance reporting, which had been poorer prior to this effort, was subsequently improved to advance the role and effectiveness of pharmacovigilance activities to support malaria control and prevention programs.

REGULATORY FRAMEWORK

Currently, almost every regulatory body in the world has developed guidelines and legal structures for pharmacovigilance efforts in their own respective countries and in some instances, for example in Europe, over the entire European Union (E.U.).

The global pharmacovigilance scenario is changing, both in terms of regulations and the efforts being undertaken by the regulators, the pharmaceutical industry, academia and health care professionals. Existing regulations are constantly being revised to adapt to new situations. New regulations are therefore being introduced in several countries.
Globalization is an important driver of the regulatory framework. In a report by Olsson et al in low to middle income countries, they found that only 69 percent of any pharmacovigilance center was affiliated with the Country Regulatory Agency. This is expected to increase over the coming years.

**USA**

The Premarketing Guidance and the Pharmacovigilance Guidance focus on pre-marketing and post-marketing risk assessment, respectively. The RiskMAP Guidance focuses on risk minimization. Together, risk assessment and risk minimization form what the FDA calls risk management. Specifically, risk management is an iterative process of:

1. Assessing a product’s benefit-risk balance
2. Developing and implementing tools to minimize its risks while preserving its benefits
3. Evaluating tool effectiveness and reassessing the benefit-risk balance
4. Making adjustments to the risk minimization tools to further improve the benefit-risk balance

In the U.S., the FDA is the responsible authority, together with the Office of Surveillance and Epidemiology and the Division of Drug Risk Evaluation that handles all pharmacovigilance occurrences.

**Europe**

The E.U. has established a legal ground for pharmacovigilance in all its member states. The non-E.U. members such as Iceland, Norway and Switzerland have all agreed also and are signatory to the E.U. Directives. The pertinent directive, Directive 2010/84/E.U. became law in 2010, but came into use in July 2012, after its publication in the Official Journal of the European Union. In accordance with the legislation, each member state must establish a pharmacovigilance system. This system is based on the local authorities, which are considered the competent authorities, and will be responsible for the collection and evaluation of the information relevant to the risk-benefit of the product under study. The new legislative framework enhances and clearly defines the roles, responsibilities and obligations for the responsible parties.

In the E.U., the Central Agency’s scientific committee will ultimately be responsible for evaluating the evidence and formulating opinions on safety concerns with at least the centrally approved product. This responsibility rests on the competent authority with locally approved products.

**India**

The legislative requirements of pharmacovigilance in India are guided by specifications of Schedule Y of the Drugs and Cosmetics Act of 1945. Schedule Y also deals with regulations relating to pre-clinical and clinical studies for development of
a new drug as well as clinical trial requirements for importing, manufacturing and obtaining marketing approval for a new drug in India. Schedule Y has recently been amended and now encompasses all post-marketing trials and clinical observations.

The Central Drugs Standard Control Organization (CDSCO), under the aegis of the Ministry of Health & Family Welfare of the Government of India, is collaborating on the creation and oversight of these pharmacovigilance guidelines and regulations with the Indian Pharmacopeia Commission, Ghaziabad. There is a nationwide program, the National Pharmacovigilance Program (NPP), sponsored and coordinated by the CDSCO, that has been given the mandate to establish and manage a database of Adverse Drug Reactions (ADRs) for making informed regulatory decisions regarding marketing authorization of drugs in India to ensure safety of drugs. The NPP, sponsored by WHO and funded by the World Bank, became operational in January 2005. Furthermore, there is close cooperation between the Indian Authorities and the WHO data bank in Uppsala Monitoring Center, Sweden, which serves 94 countries.

**Japan**

In Japan the Ministry of Health, Labour and Welfare and Pharmaceuticals and Medical Devices Agency publishes and regulates the requirements for drug products and medical devices. They use Aris Global Product (ARISj), which is a Japanese language-enabled drug safety system. The accumulation of foreign post-marketing data has equal weight as spontaneous case reporting does. Indeed, 89 percent of adverse reporting in Japan submitted to the authorities is from the manufacturers (Kimura et al.). This is different from other countries in the East Asian region, where more than 50 percent of the reports are submitted to local authorities by either the pharmacy or physician.

**Peoples Republic of China**

China has a relatively short history of drug safety surveillance compared to the U.S., many European countries and Japan. As its economy is growing rapidly, so too is its system for monitoring drug safety. The core of China’s rapidly developing drug safety surveillance program is its National Center for Adverse Drug Reaction (ADR) monitoring.

Many Chinese Guidelines were developed based on the Australian, U.S. and European systems. Originally a project
initiated with support from the Chinese Ministry of Health in 1988, the National Center was formally established in 1989. Ten years later, the National Center joined the WHO’s Collaborating Center for International Drug Monitoring (Uppsala Monitoring Center).

In 1999, the National Center joined China’s competent authority for drug regulation, the State Food and Drug Administration (SFDA), and reports to both the Ministry of Health and the WHO Center. The National Center for ADR monitoring has five divisions and a network of 32 provincial centers for ADR monitoring, all affiliated with the local provincial governments and the SFDA.

In China, like other geographies, there is a special journal, the Chinese Journal of Pharmacovigilance, which publishes scientific papers on Western as well as traditional Chinese medicine and adverse events. Although the abstracts exist in English, the full-length papers are in Chinese, thus requiring translation when other bodies are using them and trying to combine data across countries.

**Australia and New Zealand**

The Therapeutic Goods Act 1989 provides a national framework for the regulation of therapeutic goods in Australia to ensure quality, safety and efficacy of medicines. The pharmacovigilance program is overseen by the Therapeutic Goods Administration.

The New Zealand pharmacovigilance requirements have been implemented using the Medicines Act of 1981, and the New Zealand Regulatory Guidelines for Medicines, Volume 1, 5th Edition. In New Zealand, there are three agencies, Medsafe, Centre for Adverse Reactions Monitoring (CARM) and Medicines Adverse Reactions Committee (MARC) overseeing the pharmacovigilance regulations and program. New Zealand has the highest rate of reporting adverse drug reactions in the world.

**THE VARIOUS STAKEHOLDERS, CONTRIBUTORS AND TOOLS**

**Industry**

The main industrial organizations with a real interest in pharmacovigilance are the pharmaceutical companies, medical device manufacturers, clinical research organizations (CROs) and other outsourcing partners such as language translation organizations. Pharmaceutical companies, medical device manufacturers and CROs need to establish Standard Operating Procedures (SOPs) for their pharmacovigilance departments. The SOPs should also include the content published on their respective websites. Data collection is one responsibility of these departments, which in some companies report directly to senior management and even the CEO. Here language plays an important role. It is vital that the same medical terms are used and translated correctly so that
the database can be understood and disseminated worldwide. Pharmacovigilance should be conducted continuously in the pre- and post-authorization phase.

**Pre-Market (Research and Development)**
- Pre-clinical animal studies
- Clinical trials in human subjects (Phase I-III)
- Submission of regulatory file
- Review process

**Post-Market (Use by Providers and Consumers)**
- Market authorization
- Price review
- Common drug review
- Public and private drug plans and policies
- Public access
- Real world use
- Therapeutic efficacy, effectiveness and cost-effectiveness studies
- Surveillance, inspection and investigation for safety and regulatory compliance

**Post-marketing surveillance**
In Europe, the new legislation strengthens the companies’ pharmacovigilance systems without adding either administrative burden or cost. At the same time, it allows authorities to make the industry legally responsible to carry out Post-Authorization Safety Studies (PASS), and share them within three database systems: EudraVigilance, EudraPharm and the European Pharmacovigilance Issues Tracking Tool.

With this uniformity requirement, translations are extremely important so that a uniform language is used and understood. Because of these future requirements, LSPs will be very much involved and may even have to work with each other’s SOPs to achieve uniformity.

**Payors**
The health care insurance industry is another important client for pharmacovigilance data, at least in the U.S. Payors have several interest levels for these datasets.

Reimbursement can be driven by data demonstrating that a certain treatment is very effective and can result in long-term health care cost savings. On the other hand, it is equally important for the payors to understand that adverse events can increase health care costs drastically, especially if they are potentially associated with long-term harm to the patients.

Therefore, these organizations need access to pharmacovigilance databases, preferably in a language understandable to the organization. Often this requires translations from a range of languages into English.
Competent authority

In the EU, the competent authority is the regulatory authority. In some other jurisdictions the competent authority is a subset of the regulatory authority with added expertise. The charter of the competent authority thus includes the responsibility for pharmacovigilance, in which marketing authorizations are held. The competent authority has the ultimate power of retracting the market authorization, if it is deemed necessary.

It gets reported either via a country system such as the Yellow Card Scheme in the United Kingdom, or by an individual directly to the company or authorities. Sometimes, unfortunately, the occurrence of an adverse event gets reported to the media before anyone else is informed.

A way of collecting the data is using two methods of spontaneous reporting, TSR (Targeted Spontaneous Reporting) and CEM (Cohort Adverse Event Monitoring). All medical incidents (events) that patients experience while on treatment can be captured by the CEM. Those events considered noxious, unintended and suspected to be caused by the medicine are reportable as ADRs through spontaneous reporting.

TSR focuses on the collection of information on specific ADRs, with specific medicines, in defined patient groups. The report can occur in any setting and language. However, because of the need for centralization, the adverse event report may require translation into a common language. Although there are no laws and regulations that require such a practice, the need for international harmonization will require a unified language.

Assessment and investigation

Assessment and investigation is one of the most important activities during a pharmacovigilance investigation. A report of an adverse event is now part of a larger picture and should, according to the SOPs, be evaluated by a risk assessment or pharmacovigilance team. These teams try to establish the
relationship between the event and the compound or medical device. The team will also investigate the natural occurrences, and the incidence and frequency of such an event in the general population.

For example, if a cluster of an infection has occurred and is reported as several adverse events, could there be other reason besides the compound or medical device for the cluster? Has it been previously reported? Did something happen in the hospital to explain such a cluster, different from the compound’s and the device’s normal behavior?

As another example, one can evaluate the chemical name rofecoxib, the non-steroidal anti-inflammatory drug (NSAID) story, in general. Was it expected that a cardiovascular adverse event would be over-represented in groups treated with NSAIDs? Similarly, was it expected that in the Cardiac Arrhythmia Suppression Trial (CAST) study, anti-arrhythmics would cause more death than a placebo when patients with ventricular premature extra systoles were treated? Or was it expected that some patients treated for diabetes with pioglitazone would develop bladder tumors?

Many such scenarios are actual examples of pharmacovigilance at work. During the investigations that follow the events, it is important to try and establish if these adverse events, are unique, frequent, and how they relate to the natural history, not of the disease treated but of the event.

Is the frequency higher in the treated population than in the non-treated population, and of similar or higher frequency than in the general population?

An equally important question relates to the incidence of the event in the natural history of the disease. This all becomes detective work, and it is vitally important that all the parties involved speak the same language and understand each other. Translations, as well as back-translations (for the verification of accuracy, and often required or at least requested by the regulatory agencies) will be an important part of the investigations.

Companies are highly recommended to evaluate and use a qualified LSP to translate these events and the results of any investigation into the language they need to report in. It is therefore important that the LSP operates according to its own SOPs and quality assurance (QA) methods in place. These considerations are especially important when the data includes confidential patient data and other identifiable information.
Reporting

Reporting any adverse event is, besides the medical practice and need for public safety, also influenced by local cultural phenomenon. Khan et al, in 2013, found that in India, a multicultural society, the under-reporting of adverse drug events were due to fear factor (78 percent), lack of awareness (53 percent) and lethargy on the part of the reporter (43 percent).

The success of any pharmacovigilance program is highly dependent on the quality of the reporting. It must address all the issues, not only of the adverse event investigated, but place that event in relationship to the population as a whole and to the disease spectrum. Therefore, the accuracy of a report is very important. These reports will be distributed and used not only by the pharmaceutical or device industry, but also by the community at large, including insurance companies, government agencies, patients and the media. Decisions that could affect millions of people might be made on the basis of these reports, and can consequently change health care practice forever. In the best of circumstances, all these reports have been translated by a qualified LSP to ensure a high quality, accurate translation. It is very likely that a report is generated in English but may also require translation into the local language of a country in order to be accurately understood by all interested parties.

TRANSLATION

Expert language translation is critical in facilitating a smooth and efficient pharmacovigilance process. Many pharmaceutical firms have traditionally relied on their on-staff safety officers to manage the translation process, but this is becoming increasingly difficult given the rapid turnaround times required in many situations.

Additionally, the translation of adverse event reports requires the understanding of patient confidentiality rules and how they apply to adverse event reports. Safety officers may or may not understand all of the detailed rules and requirements for patient confidentiality. Patient safety officers also typically have many additional job responsibilities beyond the management of adverse event reports, a factor which can cause delays in getting the reports promptly translated.

For these reasons, it is often a best practice for pharmaceutical and medical device companies and CROs to work with a qualified LSP who understands the intent and the requirement for a common database with a common medical language.

An experienced LSP can help expedite reports and adequately participate in the creation of the worldwide database.
FIVE KEYS TO ESTABLISHING BEST PRACTICES IN TRANSLATIONS

Stakeholders can reduce their risk and streamline the translation process and costs by partnering with a qualified language services provider (LSP) that offers the right combination of expertise, infrastructure and resources to meet their needs.

To achieve this, review all potential LSPs according to five key criteria:

1. Documented, internationally recognized quality and risk management standards. A qualified LSP must have their own standard operating procedures (SOPs) to guide their team’s activities related to adverse event reporting translation processes. The SOPs and associated processes should be compliant to internationally recognized standards. Additionally, a qualified LSP should be able to demonstrate that it employs methodologies such as Six Sigma and Lean to solve problems and remove process waste, delivering a pipeline of continuous improvement activity and superior performance on key performance indicators (KPIs).

2. A high-quality, documented methodology for qualifying and managing resources. An experienced LSP should have a documented process for testing and maintaining the medical and pharmacovigilance translation expertise of its linguistic resources on an ongoing basis.

3. Web-based technology tools to foster efficiencies and process optimization. The LSP should provide Web-based tools that facilitate centralized quoting, project tracking and communications between the client and the translation team. The LSP should also offer reporting tools that identify the quantity of translation required per language. Armed with this data, the LSP can help the company implement new processes that reduce reporting translation costs.

4. Client-dedicated teams for optimal process management. Additionally, the LSP’s resources should be able to extend its translation and process expertise to its clients. For example, as in all medical areas, patient confidentiality needs to be guarded in all communications. An experienced LSP will understand what is required to properly redact confidential patient information and help the company implement compliant confidentiality practices. As part of the quality-control process, the LSP can partner with client safety officers to ensure that all patient information is properly redacted.

5. Responsive service to accommodate multiple geographic regions. An experienced LSP should have sufficient resources to support both rapid and medium reporting turnaround requirements, as driven by regulatory requirements, across multiple geographic regions. Relying on the LSP to translate adverse event reports can also free up significant employee resources.
TOOLS

Several tools are used to capture, report and place adverse events into the larger perspective.

**Databases and registries** Large databases and registries allow for cross-referencing of an event in large specific populations and can possibly identify an outlier easier and earlier, before too much harm has occurred. These methodologies allow for data mining and comparing the observed frequencies of reports for specific drug or device event combinations to expected frequency of reports for that event in the entire database.

**Epidemiological analysis** This particular tool compares reporting occurrences with background rates and can also be used to compare rates of an event within the same class of drugs or devices as well as within the same or similar indication. The major technique is “cases estimated usage,” but this is a difficult technique to interpret.

**Literature searches** It is not uncommon that literature searches or secondary sources are employed as an important tool to evaluate an adverse event. This methodology can be vast, complex and very difficult to understand. Translations become very important since literature descriptions of events may occur in any language and be published in the country where the event occurred.

**Documentation** It is important for the accuracy of the final conglomerate report that the documentation of the event is as accurate as possible. Spontaneous reports as well as cohort reports need to be investigated and verified. This is particularly important for reports that are first made public through the media and will require independent verification. Depending on the country and language the events are initially reported in, many will require adequate translation when reported to the risk assessment groups.

**Periodic safety updates (PSUR).** Companies do assemble these periodic safety updates, and they serve the same interested parties as databases and registries. Data mining is made more readily available through these updates, which focus on a particular drug or device in a particular disease. The pharmaceutical and device industries are obliged to file quarterly reports to the regulatory authorities for the first three years post-marketing approval and thereafter annually. These reports are usually focused on safety aspects and thus become part of pharmacovigilance reports.
Quality control systems. To adequately and correctly address all these issues, it is important that within each participant’s organization quality control systems are in place for the collection, assessment, investigation and reporting of the pharmacovigilance outcome. Any sub-contractor participating in these activities must also have quality control systems in place. Both false positive and false negatives are not acceptable within the area of safety, since the decisions subsequently being made will have both economical and general health consequences.

Risk management system. The risk management system is usually defined in the organization’s standard operating procedures (SOPs). As an overall requirement, risk management systems need to conform to worldwide standards that will allow all involved parties to understand and speak “the same language.” These standards apply to the reports within the system and sent to organizations, as well as reports that are disseminated for information. Only the regulatory agencies, or in very rare cases, the government makes decisions that have an impact both economically and on public safety. The language must be the same or adapted to the country in question. Forward and backward translations may be required. If a country reports an event in its own language, the report will need to be translated into the language required by the SOP and then back-translated to the original language to verify the accuracy of the first translation.

SUMMARY

The world of pharmacovigilance is growing in importance every day as medical product manufacturers expand their sales and distribution efforts in the global marketplace. Moreover, the Internet has enabled a growing number of stakeholders including consumers, medical professionals, regulatory agencies and medical product manufacturers to report on and review medically adverse effects of pharmaceutical and medical devices. Inaccurate information or the misinterpretation of reporting information can result in negative outcomes for consumers, manufacturers and the public health community in general. The best approach to minimizing this risk is to establish standard operating procedures that are built around a philosophy of accuracy, consistency and language transparency.

WORKS CITED

1. Medical Device Reporting (MDR) http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm


REFERENCES

- Green L. Postmarketing Pharmacovigilance Practice at the FDA Presentation DIA 42nd Annual Meeting, 2006
- Arora D. Pharmacovigilance obligations of the pharmaceutical companies in India. Indian J. Pharmacol. 2008; 40 (suppl): S13-S16
- Borg JJ et al. Strengthening and rationalizing pharmacovigilance in the EU; where is Europe heading? Drug Saf. 2011; 34: 187-197
- ISIS report -07/04/06 London Drug Trial Catastrophe – Collapse of Science and Ethics.