Pharmacovigilance Role in Product Licensing Transfers
**Pharmacovigilance** – involves the paradox that what is probably the most highly regulated industry in the world is, from time to time, forced to remove approved and licensed products from the market because of clinical toxicity. Why is such close regulation not effective in preventing the withdrawal of licensed products? The question has been with us from the very early days of the 1960s and remains with us today also. Therefore Global Drug Safety and Surveillance activities become more important during product/company acquisition. At times, global presence with a significant impact on cost and resources cannot be achieved only by company’s own product-pipeline; the solution is acquisition of an internationally marketed product or merger with a company.

This article will aim at increasing knowledge and awareness of pharmacovigilance licensing in international drug safety departments at the time of product/company acquisition. These activities can be divided into four core areas:

I. Due diligence on the safety of the product
II. Procedure for the exchange of safety information during the transition
III. The transfer of reporting obligations
IV. Data migration

**I. Due diligence on the safety of the product:**

Acquisition safety due diligence is defined as the analytic review and validation of business operations and financial position performed by a buyer to substantiate valuation, assess operational performance and identify misrepresentations. It reviews the available information to determine the safety of the medicinal product(s) that are subject to the transaction. It ensures that there are no outstanding issues and appropriate regulatory actions have been taken with the medicinal product(s) in Clinical and/or Post Marketed phase. This secures the company against any regulatory action being taken following acquisition. In layman’s term-it rules out the possibility of any kind of ‘surprise.’

The pharmacovigilance department should complete an assessment report after liaising with clinical and preclinical departments and produce before the legal agreement is signed.
II. Procedure for the exchange of safety information during the transition:

There should be processes for the review of safety information articles-

A. Clinical Development:
   Review of data for license submission

B. Post Marketing:
1. PSURs, Periodic Reports, Risk Management Plans/Reports- These provide an update of all safety information and Regulatory safety actions to date. Provides a company assessment on Risk Benefit. Provides an overview of the product since launch, Regulatory compliance and any responses from Regulatory Agencies.
2. Line-listings
3. Summary Tabulations- These tables can be split by System Organ Class to preferred term level detailing seriousness, sub population analysis (elderly, paediatric, pregnant patient reports, etc.), number of reports received with any possible association with drug abuse/misuse, depression, or suicide.
4. Assessment procedure for seriousness and causality
5. MedDRA coding convention
6. Compliance monitoring
7. Safety Review Group Meetings- To monitor product safety and conduct of signal detection
8. Safety Database performance and validation (against Regulatory Requirements
9. Label amendment(s) Review -To update Core Safety and Local Labels
10. Review of Organizational-Organogram: Pharmacovigilance and allied Departments
11. Review of all SOPs (in accordance to Company’s internal practice and Regulatory compliance)
12. Review internal and external trainings of Pharmacovigilance personnels
13. List of all Pharmacovigilance personnels

III. The transfer of reporting obligations

During the transfer of Marketing Authorization from one company to another, it is important to assure that the regulatory authority receives the full drug safety information without duplication which is why, close cooperation between the regulatory affairs department and the drug safety department is essential.
All the safety data (PSURs, Periodic Reports, Summary Tabulations, Line-listings etc.) and Marketing Authorization, must be transferred on a country-by-country basis. Best practice is that all the Marketing Authorizations and clinical trials must be tabulated and this table should be maintained on an ongoing basis.

IV. Data migration

It is very essential that there is a validated migration of pharmacovigilance system at the time of acquisition. Electronic data and source documentation should be migrated successfully in an acceptable format; which is determined by type of database, the volume of data, data entry conventions, type, version of the drug safety database, structure (tables and columns), customized features, dictionaries (versions) & code lists, export/import capabilities, and review of a sample export file. The time and costs associated with the transfer/copying of source documents should be explicitly addressed when planning the migration.

CONCLUSION

The quality of data plays a major role in the assessment of the trustworthiness and hence the value of the generated results, however, the results themselves reveal information on the value of the drug for the patient in the sense of its efficacy and – most importantly – its safety. True value can only be generated from a product that is both commercially promising and safe; therefore pharmacovigilance plays a key role during the product/company acquisition. However the role of drug safety departments in licensing projects is frequently underestimated in terms of resources and overall potential of a licensing opportunity.

REFERENCE:

2. Ladds G. Due Diligence; 2011.