Abstract

During the past century, medical products have witnessed a high incidence of misadventures. Some typical events examined are: Elixir of sulphanilimide (1930s'), Thalidomide (1960s'), Diethylstilbestrol (1960s') and PPA (1990s'). ADR （Adverse Drug Reacations）has become a significant problem in drug safety management due to its high incidence, inevitability and unpredictability. Based on pharmacovigilance and pharmacoepidemiology research, many countries, when carrying out risk management, have adopted Benefit-Risk analysis of marketed medical products.

ADR monitoring in our country is now in its infant period, while it faces serious social problems. In consideration of a large population, restricted condition and standard of medical treatment of our country, ADR events analyzed have been provided with common features of large number of affected patients, severe influences and high treatment expenditures. We have a large variety of medical products; especially we lack special research on herbal medicine ADR, and therefore, with existing resources, we may not find proper measures to proceed to extensive safety assessment of marketed drug. Part from this, some of our medical institutions, pharmaceutical companies and healthcare professionals do not have enough acknowledgement of ADR, which greatly impacts the ongoing ADR monitoring programme. With limited number of medical safety specialists in our country, drug benefit-risk analysis is held back at a great extent. However in recent years, the public has been paying much attention to drug safety, such as PPA event, *Long Dan Xie Gan Wan* event, Astemizol incident , etc., all of which have brought about certain drug panic among the public. Currently, enhancement of drug safety surveillance is in increasing needs by the public and ADR surveillance methods need to be updated accordingly.

By discussing and introducing advanced experience in international drug risk-management, esp. in pharmacovigilence, this essay aims at developing applicable methods and strategies for Chinese ADR surveillance, and further paving the road for national ADR monitoring development.

This essay consists of six parts:

Part I: With bibliography analysis and comparison, this essay explores the background, purpose, structure and method of this research, and re-defines the terminologies and terms referred to in this essay. All these facts show ADR surveillance is essential to the society, and our current ADR monitoring system is greatly differ from the common pharmacovigilance system that many countries employ.

Part II: compare the common pharmacovigilance system applied in different countries in terms of report systems, sources, scopes, requirements, assessments, information feedback and sanction mechanisms, and common a feature, spontaneous report, is found in their pharmacovigilance systems, while in other aspects, they differ a lot.

Part III: this essay introduces the current situation and tendency of pharmacovigilance in UMC, ICH and CIOMS, and it finds out that these international organizations have contributed a lot to ADR surveillance globalization, standardization and eletronization and international coordination as well. Therefore, competent authorities, pharmaceutical companies and medical institutions in many countries have participated in their programmes.

Part IV: by analyzing existing article, this essay introduces the pharmacovigilence system of some countries, such as U.S.A., UK, France and Japan, and further discuss about their legal basis, application and development. To draw the result, to protect the patients' privacy and improve the report quality has become the greatest challenge to European and American competent authorities. In EU countries, the monitoring method has gradually transferred form post-marketing inspection to pharmacoepidemiology research; while in U.S.A., pharmacoepidemiology research has been replaced by risk management aiming at improving the quality of report and introducing new methods or risk reduction.

Part V: by the means of analyzing articles and site inspection, this essay probes into the current situation and problems of our national ADR surveillance, and compares previous and current ADR monitoring measures and concludes the new method is greatly improved than previous one. However, it still needs improvement in its availability, practicability and criterion. The ADR surveillance has developed fast and stepped onto a new stage in recent years and built up a nationwide monitoring network. Reports received increase rapidly, but the development of this system is hold back due to limited professionals, funds and relative legal regulations.

Part VI: with the methods of comparison investigation, development analysis and SWOT analysis, this essay touches upon the topics of building ADR aiding system in our country, evaluating the unreported reasons of spontaneous report system, professional training and individual report, and further discuss the experience that we should learn from international pharmacovigilance. Part from that, this essay also takes our national situation into consideration and combine them with international experience to develop ten strategies for our national ADR surveillance.

Keywords: Pharmacovigilanc, ADR, spontaneous reporting, safety evaluation