The goal and outcome of pharmacovigilance in Taiwan

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Introduction of National Reporting system of ADRs in Taiwan

- The national reporting system of adverse drug reactions in Taiwan was established in 1998. The ADR reporting system is composed of the national center and four regional centers which collected cases to the national center till 2006 and offer educational programs periodically and were setup in medical centers located in northern, central, southern , and eastern Taiwan, respectively.
- The on-line reporting has been available since 2003 and the website(http://adr.doh.gov.tw) has been providing the information of drug safety and related issues for the public in Taiwan.
- The “Drug Safety Newsletter” has been published quarterly since the end of 2002 to disseminate information on new arising drug safety findings, ADR reporting data analysis in Taiwan, and cases in Drug Relief System.
- By well-established ADR reporting and pharmacovigilance system in Taiwan, effective drug risk management is done to achieve risk-benefit balance and safe medication use.

Goal

To provide safe medication use in Taiwan.

Objective

By means of pharmacovigilance, effective drug risk management is done to achieve risk-benefit balance. Therefore, safe medication use could be maintained.

Methods

Routine pharmacovigilance in Taiwan includes adverse drug reaction (ADR) reporting system, new drugs periodic safety updated reports (PSUR) evaluation, and drug safety information monitoring. and. By routine and targeted drug re-evaluation mechanism, the safety of drugs in Taiwan is ensured.

The Development of ADR Reporting System in Taiwan

1996 — A two-year project was carried out to collect information.

1997 — A proposal of setting up the ADR reporting system in Taiwan was submitted to DOH.

1998 —The national center and three regional centers (the northern, central, and southern regional center) were set up.

1999 — Training program for ADR reporting system was provided for medical professionals.

2000 — The fourth regional center was built up.

2001 —Establishing an ADR surveillance mechanism was required for Hospital Accreditation, and medical devices were included in this year.

2002 —“Drug Safety Newsletter” published, more than 17,000 copies were delivered to medical professionals in Taiwan.

2003 — Web-based on-line ADR reporting system was launched. An electronic database system was established for data collection and evaluation of ADR.

2004 —DOH upgraded Pharmaceutical Affairs Law, Article 45 and Article 45-1 in 2004 to include post-marketing surveillance mandatory reporting of serious adverse reactions of all approved medical products by medical care institutions, pharmacies, and marketing authorisation holders.

2006 — ADR reports collection and evaluation were centralized, and the other regional centers continued to offer educational programs.

2008 — Guidance for Good Pharmacovigilance Practice was announced.

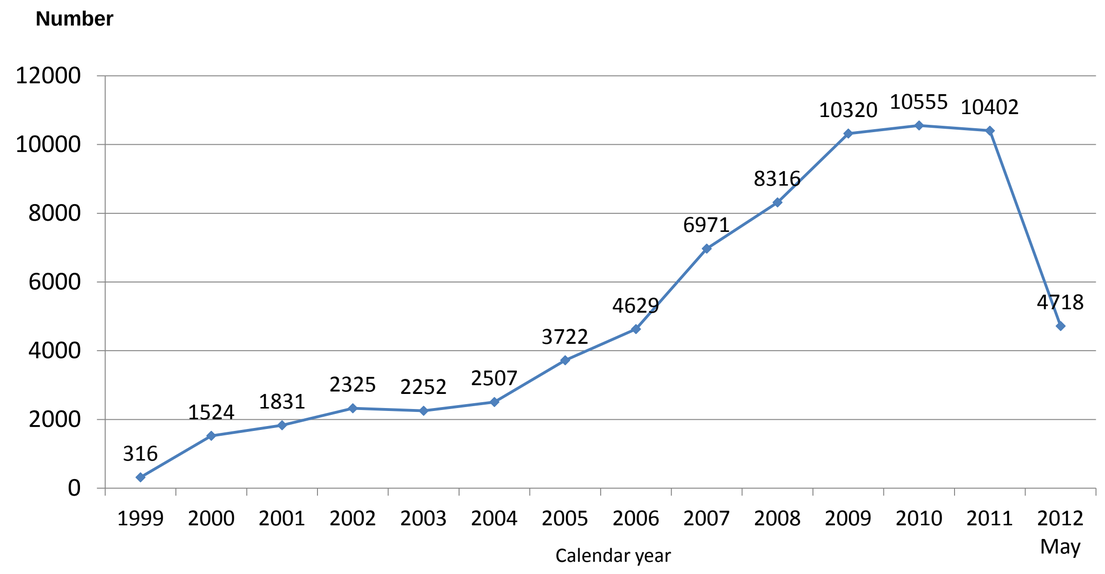
2010 — Influenza vaccine safety surveillance program was set up.

2011 — New ADR reporting system construction is in progress.

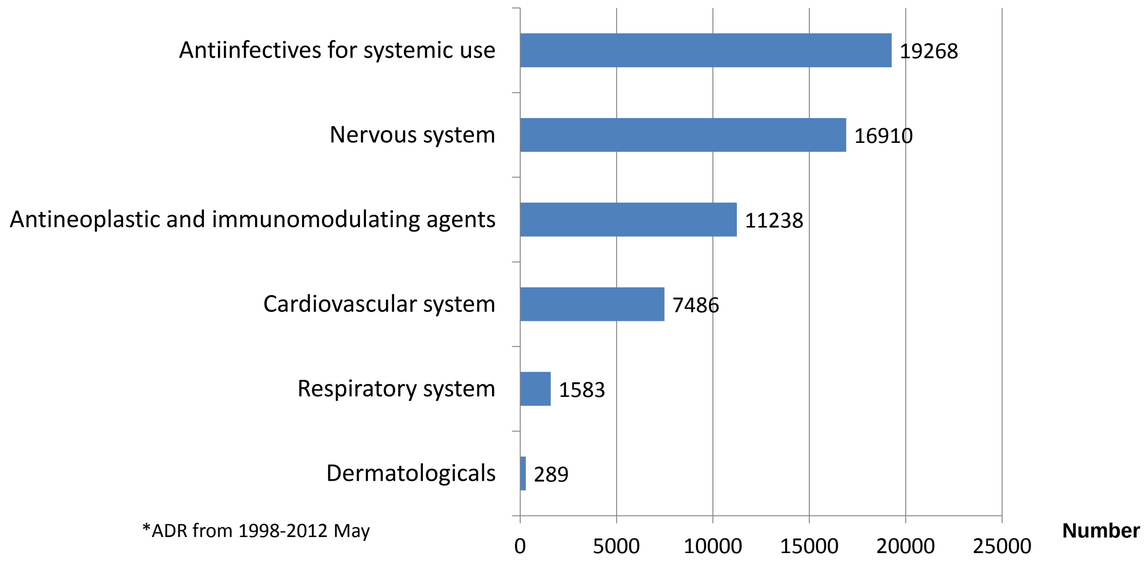
Result

- We have received more than 6.5 million reported cases since 1998 and nearly ten thousand cases were increased annually. The anti-infective drug was the majority.
- In 2011, we collected 287 drug safety information about 29 pharmaceutical ingredients and provided them for TFDA, and then TFDA announced 56 warnings. We have assessed 82 new drugs which the monitoring was finished and the seasonal influenza vaccine adverse events from 2010 to 2011. Besides, we re-evaluated 12 death cases and 12 risk-suspected drugs. All of them were discussed in the drug safety committee, and the committee suggested that one drug must be withdrawn from Taiwan market, 32 pharmaceutical ingredients required labeling changes, and risk management plans (RMPs) of 3 pharmaceutical ingredients had to be submitted .

The Number of Post-marketing ADR reports



Pharmacological Classification of Suspected Drugs



Conclusion

Efficient drug safety monitoring depended on the efforts of medical professionals, which have increased new drugs ADR reports and enhanced the quality of reporting. We will continue to communicate with drug marketing authorization holders as well as health care professionals to improve the quality of report and to enhance new drugs reporting so that pharmacovigilance in Taiwan will be a step further and safer medication use will be ensured.