The Medical Product Defect Reporting System in Taiwan

Hsien-Yu Hsiao, Wen-Wen Chen, Angela On

Taiwan National ADR Reporting Center, Taiwan Drug Relief Foundation

Taipei, Taiwan (R.O.C.)

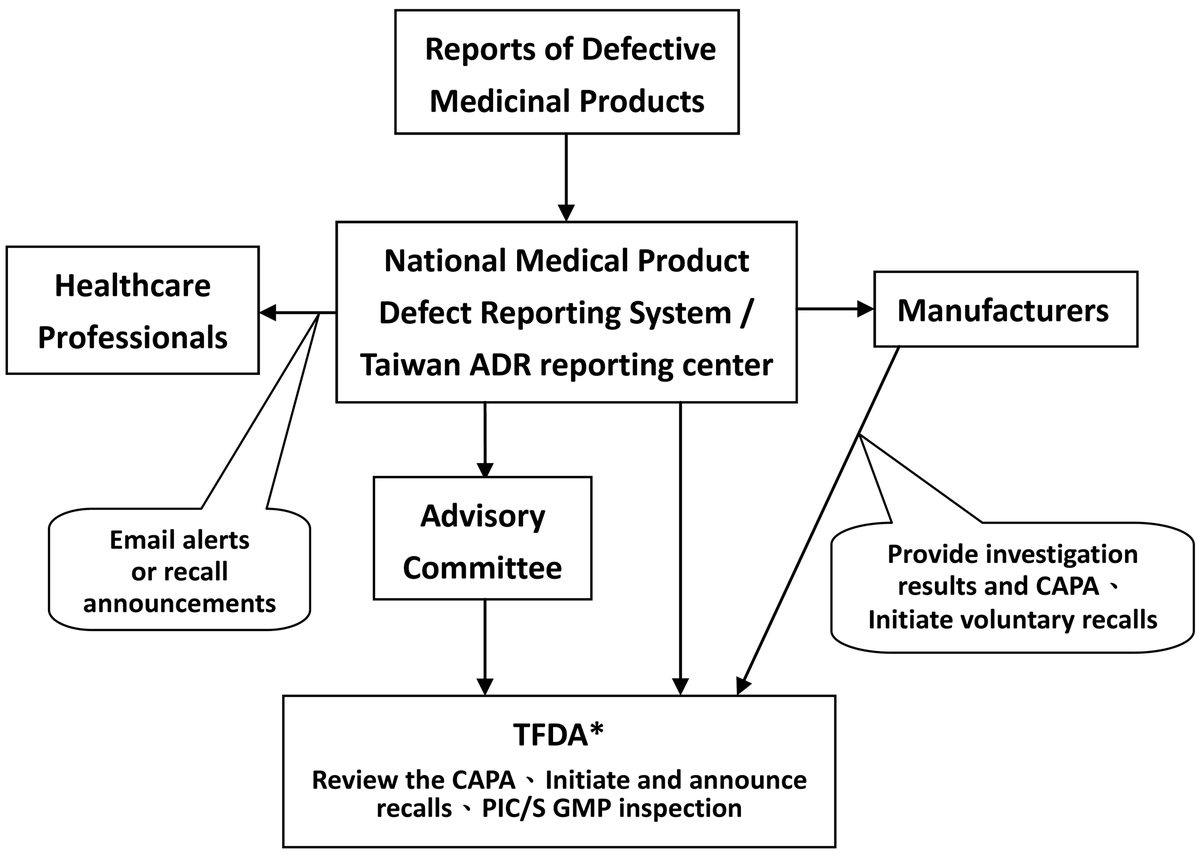
Introduction

To ensure the quality of medicinal products in Taiwan, the National Medical Product Defect Reporting System was established and is operated by Taiwan Drug Relief Foundation (TDRF), and fiscally funded by Department of Health (DOH) since 2004. The web-based system was generated for users of medicinal products to report defects, such as abnormal in product appearance, impurities, aberrant during operation, labeling or package related problems…etc. The function of reporting system includes case collection, classification, evaluation, and follow-up action.
Taiwan has been approved as an official member of PIC/S since 2013. To help Taiwan manufacturers comply with PIC/S GMP, the reporting system serves as an essential and real-time source for manufacturers to learn of their product defects. On the other hand, authorities may emphasize the specific items during the PIC/S GMP inspection according to the data from the reporting system, and realize manufacturers' management of these product defects.

The Development of Medicinal Product Defect Reporting System in Taiwan

2004- Standard operation procedures and the infrastructure of connection between different operation units in the Department of Health were established.
An on-line reporting system was generated.
2005- The instruction manual of reporting system was provided for medical professionals.
2006- The hospital contact network was established.
2008- The registration of recalls and defective medicinal products by public health bureaus was integrated to this system.
2010- High-risk defective medicinal products were defined and the operating procedures of defects with different risk level were determined.
2011- The advisory committee was organized to evaluate the cases of which the defect remains occurring after execution of corrective and preventive actions (CAPA).
2012- The project was to focus on the quality of reporting.

Theme of the reporting mechanism

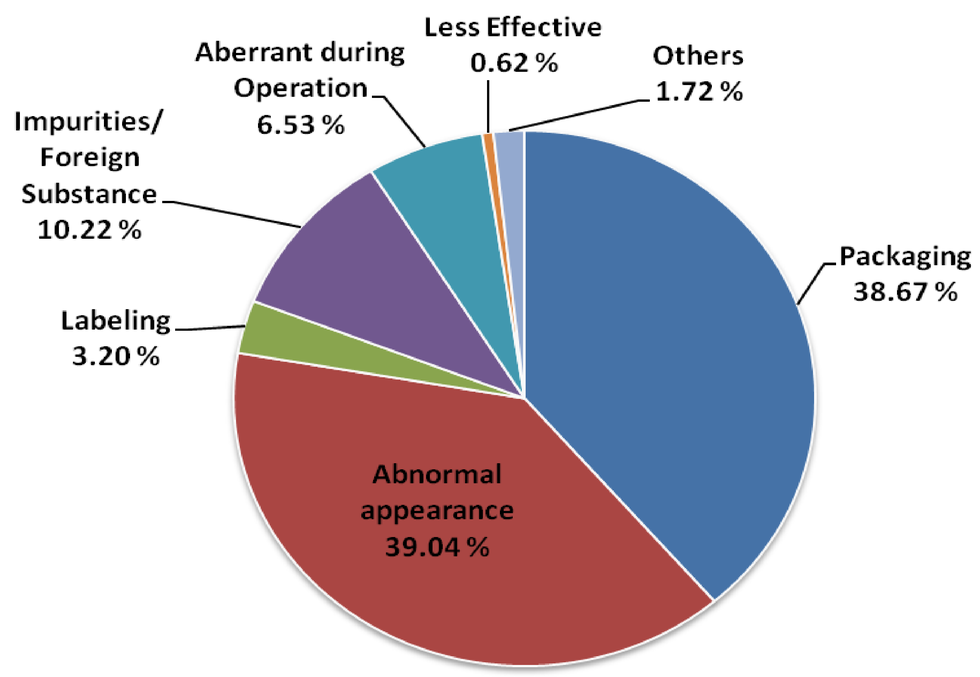


*TFDA：Food and Drug Administration, DOH in Taiwan

Analysis

We have received more than 4,000 reported cases since 2004. In 2012, there were total 773 reported cases and the "abnormal appearance" was the most predominant defect category. Among them, 181 cases were evaluated as high-risk, including contamination, impurity, deterioration, incorrect labeling....etc., and 27 recalls were initiated by this reporting mechanism. Through this reporting mechanism, 2 frequently reported products were significantly less reported in 2012.

Analysis of Medicinal Product Defects in 2012



Conclusion

Due to the efforts in the last decade, the reporting system in Taiwan has become more and more matured and well-established. Through collecting and archiving drug defects, the reporting system has become an important database for the analysis of drug quality in Taiwan. The reporting system also gives feedback to manufacturers and let them fix the defects of their product as soon as possible. Then, contact networks will be built to notify the pharmacies about the messages of product recalls and alerts. The reporting system also serves as a platform for regulatory authorities and local governments to learn of the product quality in the market and, thereby, authorities could take appropriate actions to deal with the drug defects. By the reporting system, defective medicinal products in the market are expected to be gradually minimized, and the PIC/S inspection, drug quality as well as drug safety could be simultaneously enhanced in Taiwan.