

The censoring and monitoring mechanism about the change of appearance of drug and package in Taiwan.

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Abstract

Recently, food safety have become the main concern in Taiwan. The public and government gradually attach great importance to this. However, manufactured of pharmaceuticals have always been strictly regulated in Taiwan. From the good manufacture practice(GMP) development to Pharmaceutical Inspection Cooperation Scheme GMP(PIC/S GMP). In addition, drug management policies also have international standards.

Unfortunately, some people make fake medicine sell to pharmacy and clinics in March 2017 in Taiwan. Although TFDA and pharmacists found the lot number of fake medicine for a short period of time and launched a nationwide recall , the incident gave the public some doubts about the other drugs currently in use.

There has a drug censoring and monitoring mechanism in Taiwan, but also retain some information that can be changed by the manufacturer and not to be reviewed by government such as appearance of label or package replacement. This phenomenon may lead to pharmacists lack of vigilance. In this study we explore the current censoring mechanism in Taiwan and investigated 30 prescription drugs and Over-The-Counter drugs whether the appearance of the bottles and blister packaging were in line with the content published by the Ministry of Health and Welfare licensing online search system.

By the results of this study can be found that the official online information can not let pharmacists compare the actual drug, the main reason is not to provide a complete appearance of information.

Methods

Taiwan Food and Drug Administration issued the "Pharmaceutical traceability or tracking system reporting and management approach", to master the source and flow of medicine and protect the safety of public drug usage. We analysis the 20 prescription drugs from the tracking system and the 10 Over-the-counter drugs.

• Prescription drugs

The top 20 high-need and high-cost of items was used, which was derived from the Taiwan's National Health Insurance (NHI).

• Over-the-counter drugs

The top 10 market share of items was used, which was derived from IMS Health in 2013.

We investigated whether the appearance of the bottles and blister packaging of the 30 prescription drugs and over-the-counter drugs in the pharmacy were in line with the information published by tracking system.

Results

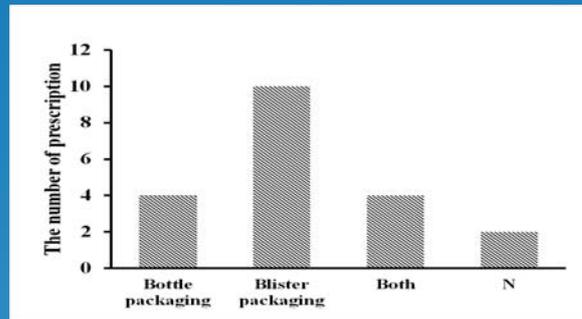


Fig 1 The integrity of prescription drugs appearance information in online search system.

(Both: Bottle packaging + Bliser packaging, N:No data)

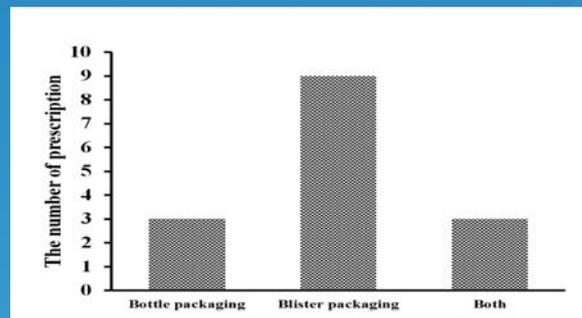


Fig 2 The actual appearance of the prescription drug is consistent with the online search system. (Both:Bottle packaging +Bliser packaging)

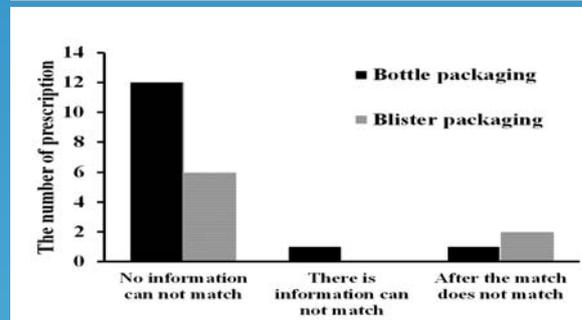


Fig 3 The reason why the actual appearance of prescription drugs does not match the online information.

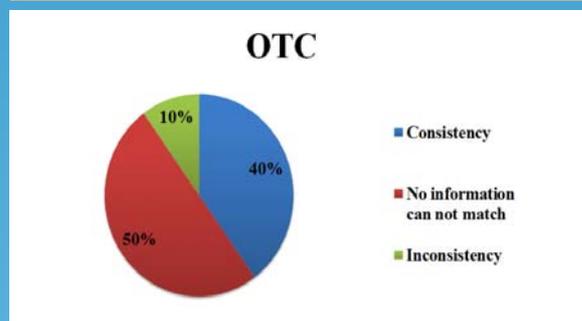


Fig 4 The consistency of the actual appearance of OTC drugs with the online information.

Conclusion

By the results of this study can be found that the official online information can not let pharmacists compare the actual drug, the main reason is not to provide a complete appearance of information, also found that some appearance of the actual drug does not match official online information . Taiwan's regulations allow manufacturers to freely change the appearance of box, label, and such changes do not need to be submitted for review again. Hope that the government and manufacturers to complete the construction of drug information system. A complete and correct information system allows the public and pharmacists to confirm the correctness of the drug and ensure the safety of the drug.