

Abstract

The standardization and readability of drug labels and package leaflets are important to clinical pharmaceutical practice, international drug business as a technical rampart, competition ability of homemade drug in international market, improvement of pharmaceutical research, and promoting our medical administration system. It is a long and important work to improve the standardization and readability of drug labels and package leaflets in our country.

Aim to improve the standardization and readability of drug labels and package leaflets in our country, through describing the status quo and evolvement on the standardization and readability of drug labels and package leaflets in the world, and comparing research among different periods, terrains, and countries. **Objective** to describe the change in time serial and the status que about the standardization and readability of drug labels and package leaflets in mainland of China, to describe the status que on the standardization and readability of drug labels and package leaflets in Macau, and put forward some strategies for improving the standardization and readability of drug labels and package leaflets in the mainland of China and Macau. **Method** to analyze the status que on the standardization and readability of drug labels and package leaflets in the mainland of China and Macau qualitatively through reference summary from CNKI, Sciencedirect and other databases, key person visiting to pharmaceutical administration officers, and world case research. The change in time serial and the status que about the standardization and readability of drug labels and package leaflets in the mainland of China and Macau were described quantitatively, and the compare on the standardization of drug labels and package leaflets between the mainland of China to Macau was also done, through comparing the probability of item labeling and item labeling summation by chi-square test. Then the strategies for improving the standardization of drug labels and package leaflets in the mainland of China and Macau were brought forward. **Result:** (1) There is distinct difference on the probability of item labeling summation in package leaflets of Chinese traditional medicine between former to now as standardization action,

and Rx to OTC. The probability of item labeling summation in standardization action is higher than before, and the probability of item labeling summation in Rx is higher than in OTC. There is distinct difference on the probability of item labeling summation in package leaflets of western medicine between former to now as standardization action, and domestic medicine to foreign medicine. There is no difference on the probability of item labeling summation in package leaflets of western medicine between Rx to OTC. The probability of item labeling summation in standardization action is higher than before, and the probability of item labeling summation in domestic medicine is higher than in joint-stock made medicine, but lower than in import medicine. There is distinct difference on the probability of item labeling summation in package leaflets between Chinese traditional medicine to western medicine, and Rx of Chinese traditional medicine to Rx of western medicine. There is no difference on the probability of item labeling summation in package leaflets between OTC of Chinese traditional medicines to OTC of western medicine. The probability of item labeling summation in package leaflets of Chinese traditional medicine and Rx of Chinese traditional medicine is higher than of western medicine and Rx of western medicine. (2) There is distinct difference on the probability of item labeling summation in package leaflets between Chinese traditional medicines to western medicine, and Rx to OTC in Macau. The probability of item labeling summation in package leaflets of Chinese traditional medicine and Rx is higher than of western medicine and OTC respectively in Macau. There is no difference in un-tangent label, and there is no difference in tangent label between Rx to OTC. There is distinct difference on the probability of item labeling summation in tangent label between OTC of western medicine to OTC of Chinese traditional medicine. The probability of item labeling summation in tangent label of OTC of western medicine is higher than of Chinese traditional medicine. (3) There is distinct difference on the probability of item labeling summation in package leaflets among domestic medicine, foreign medicine in the mainland of China, and foreign medicine in Macau. There is no difference in Chinese traditional OTC medicine un-tangent label between in the mainland of China to in Macau.

Conclusion: (1) The standardization of drug labels and package leaflets obviously heightened along with standardization action. But there are still some problems especial

the convert phenomenon between Rx to OTC. (2) The standardization level of domestic drug labels and package leaflets is higher than that of joint-stock medicine, but is lower than that of medicine from advanced pharmaceutical country. (3) There is a gap on the readability of drug labels and package leaflets between the domestic drugs to foreign drugs. One of main reasons is short of academic research. (4) The standardization and readability of drug labels and package leaflets are not satisfied in Macau. **Strategy:** The government should consummate the law system on drug labels and package leaflets according to the situation of our country, promote the pharmaceutical research base on the short of drug labels and package leaflets, and are a good steward on medicine administration. The obstruction of civilization background and language should be resolved by better translation. The different edition of drug labels and package leaflets, popularization and specialization, should be designed. The special edition of drug labels and package leaflets should be prepared for special people, for example blind people. The drug labels and package leaflets should be easier obtained by internet and traditional medium. The public research should be done on drug labels and package leaflets. All of above will be benefit to the improvement of the standardization and readability on drug labels and package leaflets.

Keywords: Label, Package Leaflet, Drug, Standardization, Readability