International Scholars Journals

African Journal of Infectious Diseases Research ISSN 4729-6836 Vol. 6 (3), pp. 001-004, March, 2019. Available online at www.internationalscholarsjournals.org © International Scholars Journals



*Full Length Research Paper*

# A report and analysis on the sampling and inspection of 50692 drugs

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Accepted 31 October, 2018

**Ensuring safe use of drugs has always been of high concern to the Chinese central and local Governments. Comprehensive and accurate evaluation of drug quality status is of great importance. This paper systematically and realistically evaluates the drug sampling inspection reports in Liaoning Province in recent three years, carefully analyzes the causes of drug disqualification and proposes some suggestions and countermeasures on the relevant issues.**

**Key words:** Drug, disqualification, Chinese medical materials, sampling inspection.

## INTRODUCTION

Drug is a special commodity related to public life and health (Wang and Zhang, 2001). Drug supervision and sampling inspection is an important part of China's drug regulation and management, an important method to guarantee drug safety in production, circulation, use and other links, an important way to find and fight against forged and fake drugs and clean up drug market environment, and a strong guarantee for public drug safety. Here, the drug sampling inspection in three years from 2008 to 2010 is analyzed and summarized as follows:

We completed the drug supervision and sampling inspection of totally 50,692 batches in three years from 2008 to 2010, in which, 5,774 batches of unqualified drugs (incl. bogus drugs) were found, with the disqualification rate of 11.4%. This paper makes the detailed analysis on the disqualification in drug sampling inspection.

## METHODS

### Analysis on disqualification in drug sampling inspection in recent three years

It can be seen that the number of batches sampled and the disqualification rates are comparable in the three years.

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### Analysis on distribution of all categories of unqualified drugs

It can be seen from Tables 1 and 2 that in disqualified drugs, Chinese medical materials (including decoction) constitute the largest proportion of 42.9%, followed by Chinese patent drugs. One important reason for high disqualification rate of Chinese medical materials (including decoction) is that inspectors can quickly and directly identify the authenticity of Chinese medical materials and Chinese decoctions with the help of senses (such as touch, sight, smell and even taste, etc) (Sui and Zhao, 2005), and additionally, the actual experience of some inspectors facilitates an efficient and targeted sampling inspection of Chinese medical materials and Chinese decoctions (Zhang, 2008). High disqualification rate of Chinese medical materials (including decoction) is a long-standing problem, but it cannot be ignored. The quality of Chinese medical materials and Chinese decoctions will directly influence clinical efficacy, and moreover, as raw materials of Chinese patent drugs, their quality will directly influence the quality of Chinese patent drugs. Meanwhile, poor quality Chinese medical material and Chinese decoction markets also adversely affect the public trust for traditional medicine, which may impact on the rise and declination of Chinese medicine industry.

### Analysis on unqualified enterprises

It can be seen from Table 3 that the disqualification rate in manufacturing enterprises is relatively low, while that in operating enterprises (incl. retail drug stores) and medical institutions is significantly higher by 13.6 and 10.2%, respectively. In recent years, with the implementation of "Drug Administration Law" and other laws and regulations, quality consciousness of drug manufacturers has been significantly improved. Meanwhile, the "good manufacturing practice" (GMP) further guides drug manufacturers to improve the management level, sense of responsibility and

**Table 1.** Sampling amounts and disqualification in each year.

| Year | Sampling batches | Unqualified batches | Disqualification rate (%) |
|---|---|---|---|
| 2008 | 16907 | 1884 | 11.1 |
| 2009 | 16680 | 1903 | 11.4 |
| 2010 | 17105 | 1987 | 11.6 |
| Total | 50692 | 5774 | 11.4 |

**Table 2.** Distribution of all categories of unqualified drugs.

| Year | Chinese medical materials (incl. decoction) (batches) | Chinese patent drugs (batches) | Chemical drugs (batches) | Others (batches) |
|---|---|---|---|---|
| 2008 | 704 | 742 | 332 | 106 |
| 2009 | 865 | 572 | 385 | 81 |
| 2010 | 908 | 614 | 380 | 85 |
| Total | 2477 | 1928 | 1097 | 272 |
| Disqualification rate (%) | 42.9 | 33.4 | 19.0 | 4.7 |

**Table 3.** Distribution of unqualified enterprises.

| Parameter | Manufacturing enterprises | Operating enterprises | Medical institutions | Total |
|---|---|---|---|---|
| Sampling batches | 1955 | 21124 | 27613 | 50692 |
| Unqualified batches | 79 | 2870 | 2825 | 5774 |
| Disqualification rate (%) | 4.0 | 13.6 | 10.2 | 11.4 |

operational capacity, further regulate the drug production activities, enhance risk management, standardize drug production process, and effectively guarantee drug quality. High disqualification rate in drug circulation and use links has the following reasons: Firstly, inadequate attention by leadership and unfavorable measures. Some medical institutions have limited space for storage of finished products, and along with the increasing number of drugs, drugs are crowded and air circulation is poor, easily leading to deterioration in drug quality; secondly, the criteria for quality control is not strict, and drug inspection and quality management system are not strictly implemented; thirdly, in some medical institutions, facilities and equipments are simple, staff mobility is high, some agents cannot be fully inspected, and it cannot guarantee drug quality.

## Analysis on disqualified items

### *Chinese medical material (incl. decoction) quality analysis*

A total of 6,900 batches of Chinese medical materials (including decoctions) were inspected, and 2,417 batches were disqualified. Amongst which, 1,725 batches (69.7%) were disqualified in properties; 472 batches (19.1%) were disqualified in identification; 401 batches (16.2%) were disqualified in ash content, as shown in Table 4.

Chinese medical material and Chinese decoction disqualification has the following reasons: Firstly, the increasing depletion of wild medicine resources (Gao et al., 2005) due to excessive picking, digging and hunting, many medicinal herbs, especially perennial herbs are fewer and smaller. In addition, some plants similar to Chinese herbal medicines are mistakenly regarded as herbal medicines. Secondly, many planted or farmed herbs are in dispersing production, so it is difficult to implement effective super-vision and inspection, resulting in uneven quality. Deterioration of quality due to improper storage, counterfeiting and adulteration are also very serious problems. Thirdly, off-site planting and cultivation time is not enough and collection misses the season, leading to decreased drug quality. Fourthly, decoction processing is not stan-dard. Some herb growers process the collected herbs locally and sell at low price, and poor sanitary conditions and non-standardized processing lead to poor quality of Chinese decoctions. Fifthly, the quality standard of Chinese medical materials and Chinese decoctions is not perfect (Shao et al., 2010), and the test items regulated in Pharmacopoeia are mostly properties, micro-scopic characteristics and TLC. It is only limited to authenticity, but can not determine their efficacy and therefore does not exclude adulteration (Zhu, 2009). It directly influences the quality of Chinese medical materials and decoctions, and also indirectly influences the quality of Chinese patent drugs. In addition, some Chinese medical material and Chinese decoction salesmen are poor in business ethics and knowledge in herbal quality (Zhang and Shang Mingyuan, 2005), and know little about the hazards of selling and using forged and fake drugs, so it is difficult to master medical material quality.

### *Chinese patent drug quality analysis*

A total of 22,081 batches of Chinese patent drugs were inspected, 2,033 batches were disqualified, and the disqualification rate was 9.2%. The disqualified items were mainly due to capacity (weight) difference, identification and properties (Tian, 2010), as shown in

**Table 4.** Unqualified items in Chinese medical materials (incl. decoction).

| Total unqualified items | Properties | Identification | Ash content | Impurities | Content | Magnesium salt | Extract | Volume ratio | Moisture |
|---|---|---|---|---|---|---|---|---|---|
| 2477 | 1725 | 472 | 401 | 270 | 248 | 36 | 25 | 22 | 6 |
| Percentage (%) | 69.6 | 19.1 | 16.2 | 10.9 | 10.0 | 1.5 | 1.0 | 0.9 | 0.2 |

**Table 5.** Disqualified items in Chinese patent drugs.

| Disqualified items (total) | Capacity (weight) difference | Identification | Properties | Content measuring | Heterosexual organic | Visible matters | Moisture | Microbial limit | Insoluble substance |
|---|---|---|---|---|---|---|---|---|---|
| 2033 | 1177 | 498 | 478 | 198 | 155 | 78 | 30 | 16 | 11 |
| Percentage (%) | 57.9 | 24.5 | 23.6 | 9.8 | 7.6 | 3.9 | 1.5 | 0.8 | 0.6 |

**Table 6.** Unqualified items in chemical drugs.

| Unqualified items (quantity) | Visible matters | Identification | Properties | Content | Capacity (weight) difference | Dissolution rate | Release rate | Loss on drying | Ash content | Microbial Limit test | Impurities |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 979 | 402 | 202 | 181 | 173 | 100 | 26 | 13 | 12 | 5 | 2 | 1 |
| Percentage (%) | 41.1 | 20.7 | 18.6 | 17.7 | 10.2 | 2.7 | 1.2 | 1.0 | 0.5 | 0.3 | 0.2 |

Table 5.

Disqualification due to capacity (weight) difference was caused by two main reasons: Firstly, in the production process, production technology, facilities, equipments and other factors cause different particle sizes; at tablet pressing, unstable velocity causes uneven particle filling, which lead to big capacity difference. Secondly, in drug distribution and use, because storage conditions do not meet the requirements (Zhang and Guan, 2008), particularly in the South, it is vulnerable to climate (such as high temperature and humidity) and other factors.

Property disqualification is mainly contributed by degeneration in gross appearance. The fundamental rea-son is that some pharmaceutical production process is not rational, such as inappropriate choice of adhesive, inadequate consumption, particle tablet too dry, and coating isolation layer not reaching isolation effect, so that drugs have lobes, piebald and other problems within the validity period. Another important reason is in drug distribution, where improper storage leads to changes in external appearance.

***Chemical drugs***

Chemical drug disqualification is mainly due to visible foreign matters in injections which occurred in a total of 402 batches, as shown in Table 6. Visible foreign matters are related to the quality of ampoules and rubber stoppers, but also closely related to production technology, raw and auxiliary material quality, employee capability and operation in clean area.

## RESULTS AND DISCUSSION

From the categories of drugs inspected, the distribution of sampling units and various disqualified drug item analysis, etc, this paper comprehensively and systematically analyzes the drug sampling inspection in our province in the recent three years. This investigation and research are completely in line with the design, comparable to the situation in other provinces, and truly reflects the current drug safety situation in our province.

Forged and fake drugs are ubiquitous (WHO, 2010), and increasingly threaten the health of people (Wertheimer and Norris, 2009; White, 1999). World Health Organization report data show that the proportion of fake drugs worldwide is about 5 to 10% (WHO, 2006; Robert et al., 2005), and is higher in developing and third world countries. To effectively reduce the disqualification

rate of drugs, the first step is to further perfect drug-related laws and regulations (WHO/ACM, 2010; COE, 2004), to make it more operational and prevent fake drugs from the sources. The second step is to improve drug quality standard (Hall et al., 2006; Gaudiano et al., 2007), the key point is to increase the quality standard for Chinese patent drugs and Chinese decoctions (Wang and Weihong, 2007; Shi et al., 2002). The quality stan-dard for commonly used Chinese medical materials and Chinese decoctions should be comprehensive, accurate, informative, and operable. The third step is to con-tinuously improve the supervision of drug distribution and use (Ping, 2010), enhance the professional quality of employees through training, and strengthen the sense of responsibility, so as to create a safe heaven for public drug safety.

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