

Understanding the expiry date on Chinese herbal medicine products

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Practitioners in the selection and purchase of Chinese herbal medicine or Chinese herbal products, more or less note the content of expiry date or shelf life on the product packaging. The expression of expiry date or shelf life may be stated differently, such as "valid until a certain period," or "Best used by a certain period," and so on. So what does the "expiry date" mean? How does it determine?

Let's imagine a scenario. A Chinese herbal medicine products has an expiry date on December 5, 2014, does it mean this product is still good on December 5, and it comes bad or unusable on December 6? What is this product? How was it produced? How come magically it turns differently in just one day? Obviously, most of the products will not be the case.

According to the Food and Drug Administration of China (CFDA), the determination of product expiry date or shelf life bases on the stability laboratory tests on samples reserved at room temperature from production. The US FDA guidance on expiry date or shelf life, "A firm may including this information (expiry date or shelf life) if it is support by valid data demonstrating that is not false or misleading." Therefore, according to both administrative departments of the two countries, in the absence of experimental data support, manufacturers should not include such information, the expiry date or shelf life, in their product labels.

Stability tests includes accelerated test, long-term test and short-term test. The principle guidance from Chinese Food and Drug Administration (CFDA) on the stability test is "The firm, who conducts an accelerated test, normally could determine a 2 years or 24 months shelf life or expiry date on its products based on the results of accelerated test; for products go through Long-term or short-term tests for stability of product quality, investigation and overall study time should be expected to cover the period of shelf life, test results should be used to compare with the test result from the date when the product was just produced (in general, the data is expressed as D_0 or D_t when $t=0$). As a reference point, the expiry date or shelf life may be determined by the longest period if its test result shows no significant change against test result from D_0 , for example, 3 years or 36 months. Manufacturers, who conducts both accelerated test and long-term test, normally determine their product shelf life or expiry date mainly based on the results from long-term test." At present, Chinese herbal medicine and Chinese herbal products from Mainland China basically have either a 2 years (24 months) or 3 years (36 months) shelf life or expiry date. For products from Taiwan, due to lack the public information on its government's regulation, the determination of shelf life or expiry date is unclear. Practitioners may directly contact the manufacturers to inquiry such information.

The 2-year or 3-year shelf life or expiry date basically provide you the information as the product has been tested for its quality stability for 2 or 3 years, the data results support the performance of the product within the validity period. As product performance two or three years later, no experimental data to support, it is not clear. Thus, the shelf life or expiry date is not a quality standards to measure product quality with in valid period and beyond the valid period. Therefore, giving product a valid shelf life without conducting stability experiments, or conducting only a 2 years or 3 years stability tests but labeling the products with 4-5 years shelf life are false fraud, it is the issue of integrity.

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