

148 Prescriptions of Kampo Medicine in Medical Insurance

Kampo or Chinese herbal medicinal preparations for ethical use are pharmaceutical Kampo products including classical prescriptions of Chinese herbal extracts, pills, powders etc. These are made through manufacturing processes involving the extraction of essences by boiling them down in water, recovery in powder form, and the addition of excipients before their conversion to pharmaceutical preparations. The term “ethical use” implies that these pharmaceutical preparations are registered in the Drug Price List for National Health Insurance(NHI). They can, therefore, be prescribed by Japanese physicians at their discretion for daily medical use under the health insurance system. Kampo preparations have a long historical background in Japan where traditional Chinese herbal medicines have been used for more than ten centuries. Today there is a heavy demand among the Japanese for these prescriptions and the benefits they can offer, all covered under the national health insurance system for ordinary medical use. In 1976 the use of Chinese herbal preparations under the national health insurance system was approved for the first time, except for 6 formulations which were approved in 1967. Today, 148 registered formulations of Kampo prescriptions are available.

History of Chinese herbal preparations for ethical use

The development of ethical Kampo preparations was possible because Chinese herbal medicines had already been commercially available as extracts in the general pharmaceutical market.

Research to develop extracts of Chinese medicinal herbs was first initiated with 4 formulations of *Minor Bupleurum Decoction* (xiao chai hu tang) etc. These were prepared for clinical trials by Takeshi Itakura in the 1940s. After World War II, Hosono, Sakaguchi et al. of the Seikoen Hosono Clinic, conducted further studies aimed at developing commercial products from them in the 1950's. Although the resulting products attracted a highly favorable clinical evaluation they were not actually marketed.

In the 1950's, pharmaceutical scientists and manufacturers began further research for the development of extract preparations. A number of extract preparations made by certain pharmaceutical companies made their way into the OTC market around 1957, and were commercially promoted at drug stores. Around that time, Chinese herbal medicines achieved a high degree of popularity, with many people buying and taking these old remedies in the guise of new drugs at pharmacies.

However, general practitioners did not accept these Kampo preparations for prescription because they were not yet approved for use under the national medical insurance scheme. In 1967, 6 products supplied by Kotaro Kampo Pharmaceuticals were accepted for registration in the NHI Drug Price List, but were less successful in gaining widespread acceptance by the public. This was partly because they were not generally known and partly because they had not been used within the Chinese medicine establishment.

Chinese herbal preparations began to be available within the national health insurance system in 1975, and 43 formulations were approved for registration. Since then, thanks to the efforts of the Japan Society for Oriental Medicine and of the pharmaceutical companies, they have gradually come to be widely accepted among general clinicians. Many other Kampo formulations were newly registered in the NHI Price List, so that the total of currently registered Kampo products is now 148.

Manufacturing Methods and Product Forms

Traditional Chinese herbal medicines are sold in various product forms. Decoction is the most common, followed by pills and powders. In Japan, Chinese herbal preparations are manufactured by extracting them from a crude drug mixture containing the relevant ingredients with hot water. The extract is then isolated using spray dryers for ultimate conversion to the pharmaceutical preparations. The most commonly employed excipient is lactose. Starch is also used, but less frequently. The preparations are marketed in various forms:

Powders	Granules
Fine granules	Tablets
Capsules	Ointment
Pill	

Of these forms, the first three are the most common on the market. Pharmaceutical companies tend to prefer certain forms for their proprietary products. For instance, Tsumura offers granule preparations, and Kanebo fine granules. Some companies are presenting some of their products in tablets. Only Kotaro employs the capsule form on a limited scale for its Coptis Detoxification Decoction, Ephara, Aconite and Manchurian Wildginger Decoction, etc.

These Kampo preparations are produced according to manufacturing methods approved by the Ministry of Health, Labor and Welfare; and are subject to strict regulatory control in terms of concentration, composition and other quality requirements.

Among the classical preparations preparations, for example *Angelica and Peony Powder* or *Cassia Twig and Tuckahoe Pill* were developed as powders or pills. Ethical Kampo preparations, even if their original form was a powder or pill, are without exception preparations obtained as extracts from hot water. The reason for this procedure is, that it eliminates bacteria or fungi contained in the crude drugs and markedly decreases the concentration of heavy metals and pesticides. Microorganisms and fungi are killed and the concentration of heavy metals and pesticides decreased during extraction to one tenth of their initial concentration.

The additional combination of chemical substances with extracted Chinese herbal essences is not performed, because it is required to maintain the purity of the contained essences. In view of the need to ensure the purity of the essences contained in the preparations, no crude powder admixture to the product is admissible.