

China's new quality control

In the first of new series on China, *FF&N* looks at how the home of Traditional Chinese Medicine is seeking to shed its image of poor quality control on its herbal products. SHANE STARLING investigates

The modernisation of China's traditional medicines industry continues to gather pace as its government-sponsored Good Manufacturing Processes (GMPs) and Good Agricultural Processes (GAPs) policies begin to take effect.

Back in the 1980s, the Chinese government recognised that its TCM industry needed upgrading if it was to compete in the international market but only now are the benefits of this strategy coming to fruition.

All companies involved in the manufacture of TCM must comply with guidelines laid down by China's State Drug Administration (SDA) by 2004 and farms producing raw ingredients must comply with SDA-imposed standards by 2007.

By the end of last year, 1,470 companies had registered for GMPs while 570 failed to meet the standards. 3,000 applications are still pending.

"With the full implementation of GMPs and GAPs in the next few years, we expect Chinese botanicals and their extracts to significantly improve in quality," said Dr Albert Wong, president of the Modernised Chinese Medicine International Association (MCMIA), a Hong Kong-based trade association. "Meanwhile, Hong Kong, with its long tradition as the most important exporting city of Chinese herbs and proprietary Chinese medicines, is assuming the role of gatekeeper for their quality with the help of modern technology."

Larry Wong, chairman of the Modern Medicine Foundation, a US-based body that promotes the exchange of knowledge between the East and West, said the changes

would force many smaller players out of the Chinese TCM industry, but that they were necessary if the industry was to survive.

"Manufacturers with money are responding well," he said in regard to the imposition of GMPs. "But many manufacturers don't have the money and they might close down. The larger companies that remain are ready to increase production and will take up the slack."

It has been estimated that companies will need to spend approximately \$2.4 billion to upgrade their facilities.

While some companies are unhappy at being forced to change their work practices, Larry Wong said the SDA would not backtrack from its implementation plans and knew from the outset there would be casualties.

"Products that don't meet the GMP standards will simply not be allowed onto the market," he affirmed. "China needs quality control for both the export industry and the domestic market. Right now, the standards are not very high and the quality is not very good. For this reason, the international image of TCM has not been very high."

QUALITY AS A COMPETITIVE EDGE

Both the government and the industry are concerned about the loss of competitiveness internationally, according to Bill Liang, managing director of California-based China Healthcare Consulting. "They strongly believe that China should have a very distinct advantage in TCM and they are very disappointed to see the world market being dominated by other Asian competitors," he said.

Only once GMPs and GAPs are in place could the industry hope to improve its image and start to build on its current five per cent share of the world botanicals market, according to Larry Wong. An estimated 40 per cent of the Chinese population take TCM regularly.

Wong highlighted the importance of implementing GAPs in conjunction with GMPs. "There's no point in having high-level GMPs if the quality of the ingredients is poor. That's why it is important that these two initiatives are put in place simultaneously," he noted. "The GAPs are basically a set of guidelines for herbal farmers to follow," he pointed out. "There will be qualified people at the sites to pass on the knowledge to the farmers as to the best way to grow the various kinds of herbs."

"It will be difficult for the small farms because as a rule they are further behind than the bigger farms. They don't have the machinery, the technology or the capital to make the necessary changes, so many of them will amalgamate or be taken over by larger farms."

Clinical trials are also being funded to provide the kind of scientific evidence Western markets demand for its medicines.

Larry Wong said China welcomed Western interest in TCM. "The Chinese government is happy to have Western companies come in and set up operations or joint ventures to help raise standards," he stated. "Western companies have valuable knowledge, especially about GMPs, and the Chinese government is keen to exploit this as much as possible." 