Republic of the Union of Myanmar

Providing Affordable Traditional Medicine

Traditional medicine has been used for generations in Myanmar, and recently enacted policies have proven advantageous to help people throughout the country access traditional medicine. Utilizing the country's abundant natural resources, Fame Pharmaceuticals has combined modern and traditional techniques with innovative packaging and eye-catching brand names to develop and distribute traditional medicine that is safe and affordable.

Background

Traditional medicine has played an important role in the history of the Republic of the Union of Myanmar (Myanmar). Although the use of modern medicine has dramatically increased, it is not easily accessible for much of the population due to prohibitively high costs and limited availability, especially in rural areas. Even when it is readily available, many people are reluctant to use it because of cultural differences and concerns



The headquarters of FAME in Myanmar (Photo: FAME)

of side effects. Traditional medicine has been used for generations and is more affordable and easily obtainable – even in rural areas – therefore it continues to be widely used and plays a significant role in health care in Myanmar.

In 1997, the World Health Organization (WHO) drafted the Declaration on Health Development in the South-East Asia Region in the 21st Century (the Declaration), in which member states laid out their proposals for health reform. One important topic was that of traditional medicine, and the government of Myanmar has taken measures to increase the role that traditional medicine plays as an internationally accepted and natural alternative to modern medicine. As part of this initiative, the Myanmar Ministry of Industry and the Myanmar Food and Drug Administration (MFDA) actively promote policies that are advantageous to private pharmaceutical companies in the manufacture of high quality traditional medicine. One company that has benefited from such policies is FAME Pharmaceutical Company (FAME), which is a privately owned Yangon based manufacturer and marketer of traditional herbal medicines.

In Myanmar, under the 1992 National Drug Law only government owned factories are authorized to produce prescription drugs, which ensures quality and reduces

health risks. FAME started in 1994 as an authorized distributor of medicine produced by the Myanmar Pharmaceutical Factory (MFP), one of the two government owned factories that produce prescription drugs (MFP started to privatize in late 2013). In line with the government's desire to promote traditional medicine, in 2002 FAME started production of traditional medicine as a substitute for expensive imported medicine. The company's high quality, low cost products earned it a good reputation and the FAME brand became very popular. The company is now the leading manufacturer of traditional medicine in Myanmar and also enjoys a profitable export business.

Age-Old Wisdom Mixed With Modern Technology

Taking advantage of positive conditions in the health industry as a result of the Declaration, FAME established a research group in 1997 to develop traditional medicines that would meet international quality standards. The result of this research was the creation of FAME's first product: *FAME Urocrush*, an effective herbal treatment for kidney stones made from four medicinal plants that grow in



The company's first product, Urocrush (Photo: FAME)

Myanmar. Pilot production took place in January and in February 2002 manufacturing started. FAME Urocrush was met great success, and research development (R&D) continued towards the creation of traditional medicines for six major diseases: diarrhea, diabetes, dysentery, high blood pressure, malaria and tuberculosis. Subsequent products were met with similar positive results, and the company's R&D into traditional medicine has become the cornerstone of FAME's business and is essential to its growth.

FAME continues to use modern technology in its research programs to innovate quality organic

medicines under the guidelines laid out by the Declaration that treat many common disorders. The organic nature of the company's products is of particular importance to attracting customers. Because of the widespread use of traditional medicine in Myanmar, organic products can bring people peace of mind, ensuring them that the products are safe and similar to what they have been using for generations. FAME therefore puts significant effort into its R&D to ensure that it develops organic medicines that meet customer expectations and needs, and even bills itself as more of an organic farm than a pharmaceutical company. In March 2010, FAME received certification from the Myanmar Organic Agriculture Group recognizing its adherence to organic production requirements.

To ensure that products remain organic, the company launched the FAME Organic Pharm, a large compound in Pyin-Oo-Lwin that provides the company with the majority of its raw materials. Over 30 indigenous plants are cultivated at the FAME Organic Pharm according to farming practices laid out by the International Foundation for Organic Agriculture Movement (IFOAM), an international organization based in the Federal Republic of Germany (Germany) that assists and promotes the use of organic products. Enjoying certification from the Myanmar Organic Group and meeting the production standards of IFOAM, the agricultural

farm ensures that all of FAME's products are free of synthetic chemicals, fertilizers, and residual chemical insecticides.

In its efforts to expand globally, FAME has received certification from Australian Certified Organic (ACO) of the Commonwealth of Australia (Australia). ACO is Australia's largest certifier for organic and biodynamic produce, and is recognized as an accredited certifier by many countries, including Canada, Japan, and the United States of America (USA). Certification through ACO brings with it market access in those countries in which ACO is accredited. For example, ACO is an accredited organic certifier with the United States Department of Agriculture (USDA) and offers "USDA Organic" certification under USDA's National Organic Program. Successful certification allows the use of the USDA Organic logo and entrance into the USA market. In 2014, two of FAME's production facilities – those located in Mandalay and Yangon - received USDA Organic certification for many of the company's crops and products produced at FAME's products are certified organic by ACO (Photo: these facilities.



FAME)

Research into extraction methods, efficacy experiments, and quality control are all integral components to the company's success. Partnerships and collaborations are also used to facilitate the development of new medicine, and FAME works with scientists and researchers from the University of Yangon, Yangon Technological University, and the Department of Medical Research of the Ministry of Health. Laboratories with cutting-edge technology in Germany, the Swiss Confederation (Switzerland), and the USA are also utilized in the testing and quality control processes.

Another important aspect of FAME's broad R&D approach is the publication of monthly journals on medicinal plants and the related diseases they treat. The company also shares its R&D findings with physicians and patients through local and international seminars, workshops, conferences and exhibitions, which provide employees and researchers further means to maximize R&D effectiveness and quality control.

A Traditional Approach

According to traditional beliefs in Myanmar, there are 96 diseases that afflict humans. Myanmar traditional knowledge and medicine is believed to be able to cure all of these diseases by using ingredients such as fresh or dried roots, stems, leaves, buds, and flowers. With its beginnings in similar traditional medicine systems of neighboring countries, traditional medicine in Myanmar has been enriched by

traditions, adaptations, and adoptions of different practices throughout the centuries.

Traditional medicine continues to be widely practiced by the majority of the population, partly as a supplement and partly as an alternative to modern medicine. Traditional knowledge of indigenous medicine is handed down through generations, and was developed according to personal experiences and traditional beliefs on the action of medicinal plants. The Myanmar government has been actively involved in preserving traditional knowledge by teaching it through various institutions since 1976. In 2001, it established the University of Traditional Medicine to confer four-year academic degrees in traditional medicine. By the mid-2000s, there were over 16,000 traditional medicine practitioners in the country.

In 2010, following a period of development FAME started production of *Starnise*, an antiviral drug that uses *shikimic acid* from *illicium verum*, commonly known as the star anise plant. Tapping into the traditional uses of the plant, the company was able to develop a drug with an active ingredient that has been identified by the WHO as being effective in combating various forms of influenza virus strains (such as H1N1 and H5N1). This is but one example of the abundance of traditional medicinal knowledge in Myanmar that has served as a catalyst in the development and commercialization of FAME's products. Manufactured only with organic materials, the company has tapped into generations of indigenous knowledge to not only make traditional remedies more accessible, but to also introduce new innovations at an affordable price.

IP in Action



FAME produces a variety of products, including organic honey (Photo: FAME)

A strong brand name backed up by innovative products has been one of FAME's most important success factors. To protect its brand name and products from copying and infringement, FAME registers each new product name it develops with the Yangon Registration Office of the Settlement and Land Records Department (SLRD). In absence of an official trademark law (as of 2014), SLRD is the authority through which trademarks are registered in the country be means of a Declaration of Ownership under Direction 13 of the Myanmar Registration Act. FAME has over 70 trademarks declared under Direction 13, the first of which was for FAME Urocrush.

Trade dress is also important because consumers are able to quickly identify FAME's products. Since copying package designs is a common infringement, the company uses special anti-counterfeiting technology in its packaging. In addition, trademark and design applications are made in target international markets, and FAME has an in-house intellectual property (IP) management group to oversee all domestic and international applications.

Bringing Medicine to Those Near and Far

All of FAME's products are manufactured at its factories in Yangon (Myanmar's largest city), which has received international recognition for the quality of its production and management systems. In 2002, the company received certification for its quality management systems from the International Organization for Standardization (ISO), the world's largest developer of international standards based in Switzerland, in the form of ISO 9001:2000 and the subsequent revision, ISO 9001:2008, in 2009; ISO 14001:2004 (2006) for its environmental management systems; and OHSAS 18001:2007 (2006) certification for its occupational health and safety systems related to its research, development and manufacturing of alternative medicine products. There are over 300 employees working at the factory, including scientists, doctors, pharmacists, biochemists, botanists, microbiologists and traditional medicine specialists.

Ninety percent of manufacturing materials are taken from domestic sources, including from the company's organic medicinal herb farm located in northern Myanmar. FAME operates pharmacies in the major cities of Myanmar, and its products are distributed to more than one thousand pharmaceutical locations throughout the country. FAME products are also distributed internationally in Southeast Asia and other countries such as Germany, the State of Kuwait (Kuwait), Japan and the Republic of Korea (ROK).

FAME divides its products into five categories, which each meet a specific need: spirulina (a microscopic algae containing many nutrients) products, herbal medicine, honey and bee products, consumer products and cosmetic products. Spirulina products include Spiru-Emblica (an antioxidant supplement) and Spiru-Garlic (a cholesterol lowering agent). The company is a leading producer of herbal medicines, some of which include Diarstat (anti-diarrheal), DiabeHerb (anti-diabetic) and Plasmogin (anti-malarial). For honey and bee products, popular FAME innovations include Organic Honey, Tinospora Honey (an anti-inflammatory agent), Royal Jelly (an anti-aging agent), and Bee Pollen. Consumer products based on medicinal herbs include Neem Skin Cream and Nemoderm, a natural antiseptic. The company's also has a line of cosmetic products that are marketed under the Ladymax brand, which include anti-wrinkle cream and anti-aging gel.

Practicing Social Responsibility

Developing new medicines based on traditional knowledge and making them affordable and accessible has had a positive social impact on the population's ability to access medicine in Myanmar. Because of the important role of traditional medicine, and also because imported Western medicine is prohibitively expensive, people have access to affordable alternatives to meet their health care needs. With the utilization of traditional medicine growing every day, safe, high quality products are essential. Through commercializing its products, FAME has been able to meet a very important social issue in Myanmar and provide for the health and wellbeing of many people, who would otherwise have gone without any form of medical care. Taking their role in the community further, FAME prioritizes the implementation of corporate social responsibility initiatives through the company's Volunteer Task Force. By taking a responsible approach, the company has been able to ensure that FAME's activities make a positive impact on the environment, consumers, the

company's employees, and local communities. One such initiative is through significant and annual contributions to the Myanmar Medical Association Support Group for Elderly Doctors, which provides elderly doctors in need with essential medical, social, and financial care. In addition, FAME makes regular contributions to non-profit organizations and major hospitals throughout Myanmar.

Education is a vital tool with which a positive societal impact can be made, and FAME has used its resources, know-how, and expertise to reach out to the public in an educational capacity. These include a series of programs on health topics shown on the Myawaddy television channel, one of the country's largest, and educational events throughout Myanmar to educate the public on health welfare issues.

Starting in 2005, FAME released a series of Video Compact Discs (VCDs) highlighting various health concerns, such as the dangers of ultraviolet light and how viruses work. The themed programs feature a medical professional discussing the topic in an easy to understand way, which gave rise to the name of the series – Health Talk. As of 2014 FAME released 9 Health Talk VCDs since the start of this program. In addition, in 2011 the company launched FAME Publishing House, which publishes a series of educational books on traditional medicines. Topics include healthy living practices and detailed information about medicinal plants, and by 2014, 10 books were published. These outreach efforts have been exceedingly beneficial, as many people in rural areas were without any type of access to health related educational services. This has in turn helped such individuals make more informed decisions about their personal health care.

Going Forward

Originally only working as a domestic distributor for MFP, FAME has become one of the largest traditional medicine manufacturers in Myanmar. Enjoying continued growth domestically and internationally, the company's annual turnover has reached over US\$2 million. By 2014, FAME's products were sold in countries within close proximity to Myanmar – such as the Republic of Singapore, Malaysia, the Kingdom of Thailand, ROK, and Japan – and further away, such as Germany and Kuwait.

FAME's dedication to quality products led to WHO Good Manufacturing Practice certification in 2003. Furthermore, the company's innovations have also brought it international recognition, such as becoming a finalist in the Corporate Social Responsibility category of the Association of Southeast Asian Nations (ASEAN) Business Awards (2010). Thanks to the company's innovative use of technology, in 2013 the solar thermal drying rooms at FAME's Yangon factory



The company has been recognized internationally for its innovations, such as at the 2010 ASEAN Business Awards (Photo: FAME)

were recognized by receiving an award in the ASEAN Best Practice Competition for

Energy Management in Buildings and Industries at the 2013 ASEAN Energy Awards. In a considerably short time, FAME has become internationally known for its innovative products and commitment to social responsibility.

Providing an Unmet Need

In many parts of Myanmar, economic circumstances have made it difficult for people to access modern medicine. Recognizing the need for a viable alternative to expensive imported drugs, FAME was able to use the abundant natural resources of Myanmar to develop traditional medicine that is affordable and easily accessible. Not only has the company enjoyed growth and access to international markets through its innovative IP, but its products have also enhanced the wellbeing of people who would otherwise not have access to medicine.