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Uplifting ayurveda medicine system

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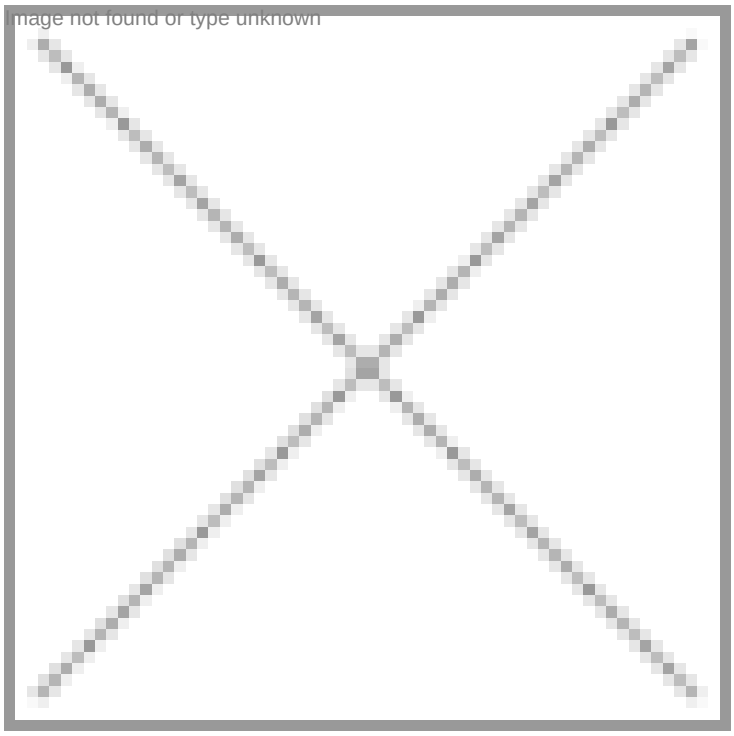

BioSpectrum peeps into the hallowed precincts of this well-known institution in Kerala to report about the transformation that is taking place at a frenetic pace

It was a risky step. Because under the British rule, the allopathic system of medicine had started to make inroads into the Indian society. People were attracted by the 'magic' of instant cure offered by modern medicines. For, the rigorous, holistic regimes prescribed for ayurveda medicines required long gestation period to show results for many ailments. And many of these ayurvedic medicines had to be prepared through elaborate processes at home from a variety of ingredients.

But Vaidyaratnam PS Varier seemed to have hit the winning note. Vaidyaratnam is a title meaning 'jewel among doctors'. Patients flocked to his medicine shop. Maybe because he gave them ready-to-eat ayurvedic preparations. The drudgery associated with home-based preparations was eliminated. Today, The Arya Vaidya Sala symbolizes the ayurveda system of medicine and Kottakkal is no more a sleepy town. People from all over the world flock to Kottakkal for a host of treatments. The Arya Vaidya Sala has now over 14 branches with hospitals and research centers, and countless marketing units. It has a turnover of around Rs 80 crore and exports substantial quantities of medicines to foreign markets.

The good doctor's successors are not resting on the laurels. If readymade herbal medicine was the attraction of the Vaidya Sala in the early 1900s, in the 21st century, it is the biotech initiatives which are making news now. Experts believe that these initiatives offer a hope for reviving India's traditional system of medicine.

"The Arya Vaidya Sala is moving in a big way with a plan to modernize Ayurvedic medicines through biotechnology," says AR Sankaranarayanan, general manager, Arya Vaidya Sala.

However, it did not happen suddenly. In 1998, CSIR director -general Dr RA Mashelkar approached Arya Vaidya Sala with a proposal for collaboration in the Ayurveda sector. The idea was to sort out certain active principles behind individual ailments and new medicaments. Arya Vaidya Sala, as conventional practitioners of ayurveda, initially approached the project with a sort of scepticism and apprehension. Ayurveda as a medical system does not talk about single herbs; instead it talks about poly-herbal combinations. It was Dr MS Valiathan, a pioneering biomedical researcher, who intervened and convinced that they need not compromise on the conventional systems. He added that if they don't take the right step in this field, it would be a multinational who will walk away with the benefits by entering the field. And finally on February 1, 1998, Dr RA Mashelkar came to Kottakkal and the MoU was signed between CSIR and PK Warrier, the managing trustee and chief phycisian of the Arya Vaidya Sala.

The MoU stipulated that based on the conventional knowledge, Arya Vaidya Sala would make an attempt to develop a modern medical treatment system which would be accepted universally as a therapeutics agent satisfying all global standards and quality.

Getting global recognition is a key goal because no major country has so far recognized ayurveda or any other traditional systems of medicine for generic purposes. The Chinese medicine preparations too face the same problem in entering the markets in the developed countries.

The Indian government has learnt its lesson from the patenting of the neem plant in the USA. It has recognized that Indian herbal remedies are much sought after in the West, and that there is a need to protect them. Instead of closing the doors on foreign biotechnology companies, the government has come up with a profit sharing mechanism to ensure that Indian communities benefit from the commercialization of Indian herbal drugs.

The CSIR- Arya Vaidya Sala program aims to develop bioactive molecules and then establish the standardization procedures and improve the processing and preservation techniques of ayurveda medicines.

Changing scenario

Things may have started to change gradually. Recently Russia has recognized the ayurvedic system of medicine. India and Russia will soon sign a memorandum of understanding setting up ayurveda's Panchakarma treatment for victims of the Chernobyl nuclear disaster. This cooperative agreement was announced at the World Ayurveda Congress, held recently in Kochi. Kottakkal Arya Vaidya Sala will provide technical support for the venture. The U. K., Germany, France, Sweden, Austria, United States and Italy have launched schools of alternative medicine, which is primarily the Indian system of medicine. Additionally the World Health Organization has explored the potential of Ayurveda and found it efficacious in not just curing diseases but also for preserving health.

"We provide some classical knowledge and classical materials, not raw materials but finished products, as per some classical formulations," said TS Murali, CSIR-IICT& DST Project Head. The standard protocol tests for vaccination is done at IICT (Indian Institute of Chemical Technology), Hyderabad and the CSIR lab screens the end products to check whether it has promising results. Preliminary research results indicate that a few molecules or herbal formulations with sufficient efficacy have been identified. The process is in progress to set up a pilot plant which is expected to be completed by September.

The members of the CSIR-Arya Vaidya Sala project include the project head, who is a physicist, two physicians, a biochemist and five chemists. There is also a herbal quality control section, which has two wings. The first includes a group of physicians who decide the herbs depending on the classical specifications. The second group does the chemical analysis based on the pharmaceutical standards put forth by the government. The R&D department is also engaged in other kinds of in-house research like stability factors, setting up of new standards and trying to develop new medicines. The Vaidya Sala has set up three labs for R&D work. CSIR has short listed about 20 different disease conditions like cancer, ulcer, arthritis etc under this project. Efforts are also on to formulate memory enhancers and drugs that could be used in ailments related to central nervous systems. Clinical trials in cancer and rheumatic arthritis are being carried out at the charitable hospital run by the Vaidya Sala. The researchers here have collected patient data from about 900 cases. The data analysis process is now on. They have also set up a pain and palliative care clinic at the Calicut Medical College hospital. This is recognized as a model pain clinic by the World Health Organization for developing countries.

The five-year project period is nearing its end. "We will mutually extend it for another five years," said the project head. Two of the molecules have already been identified. "More importantly we have found that is not the fraction but the original combinations that has an effect," said a team member requested anonymity. "This is a gratifying experience for us," he said.

Arya Vaidya Sala is not just into popularizing of the ayurvedic medicines by modernization and standardization, but also into plant biotechnology research. The Arya Vaidya Sala cultivates medicinal plants at Kanjirapuzha and Kottappuram in Palakkad district on a large scale. To help the correct identification of herbs, a research garden was established on eight acres of land near the charitable hospital. This garden at Kottakkal has around 1000 medicinal plants.

As an initiative in the plant biotechnology research, a project has been started with the support of the Department of Biotechnology (DBT) to establish a germ plasm bank for ayurvedic medicinal plants at Arya Vaidya Sala. Started in March 2002, the major objective of the project is to explore, identify, document and collect the rare, threatened and endangered medicinal plants used in Ayurveda and other systems of medicine from Kerala, Tamil Nadu, Karnataka and Andhra Pradesh. The project, which has a deadline of three years, will also study the extent of rarity of medicinal plants and their intra species variation. The Centre for Medicinal Plants Research of the Vaidya Sala is also setting up a gene bank of rare, endangered and threatened medicinal plants having components of in vitro and seed gene banks. Building up of a herbarium of dried plant twigs with all relevant information connected to their identification and setting up of museum of medicinal plants, which will serve the purpose of a library for the future reference, are also part of the project.

"Our aim is to collect and protect rare and endangered medicinal plants. We have roughly short-listed 150 plants, with all accession details, to display in the germplasm bank," says Dr Indira Balachandran, principal investigator of the DBT Project. "The project has completed a year and we have already made quite a few collections from the primary sources as well as a few from the secondary sources" she said. The next step is to transplant them in June when the rainy season begins. A couple of green houses are ready for the purpose. It is important to avail the genuine medicinal plants for the future.

"We are soon going to have a full fledged biotechnology division. We are going to appoint Phytochemists and biotechnologists probably by June or July, " added Dr Indira Balachandran. Lakhs of seedlings of rare medicinal plant species, which are not available easily, can be multiplied using micro-propagation techniques.

The Kottakkal Arya Vaidya Sala has come a long way in the preservation and promotion of ayurveda by providing genuine medicines, treatment, education and research facilities for the benefit of the world. They could have continued in the same way. But then, the scope of popularizing ayurveda in the global market would not have come into existence. The Vaidya Sala looks at uplifting ayurveda to the status of cardinal health care system all over the world. And the biotechnology intervention will surely help it to achieve their goal.

Legal hurdles

Though Indians have been using several indigenous systems of medicine, they have caught global attention only recently. Perhaps due to disenchantment with many allopathic medicines which cause innumerable side effects. The foreign tourist boom in Kerala and the hardselling of ayurveda has spawned new set of users for this sector.

Yet, it is unlikely that ayurveda and other traditional Indian medicines will adorn the chemists' shelves across the world soon. For, the drug regulatory systems imposes rigorous quality standards on such products to ensure that they do not cause any harm to the consumers.

In India, companies have launched many herbal remedies in the market. The Drugs & Cosmetics Act, 1940 (the "Drugs Act") and the Drugs and Cosmetics Rules, 1945 (the "Drugs Rules") prescribe the standards and quality, and regulate the import, manufacture, sale and distribution of all drugs including ayurvedic medicines in India.

Under the Drugs Act, an ayurvedic drug includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in the authoritative books of Ayurvedic, Siddha and Unani Tibb systems of medicine, specified in the First Schedule" of the Drugs Act. (Section 3(a) of the Drugs Act)

The Drugs Act prescribes a particular standard for manufacturing an ayurvedic drug for sale or for distribution. The drug manufactured should comply with the standards for identity, purity and strength as laid down in the editions of ayurvedic pharmacopoeia of India. (Section 33 EEB of the Drugs Act r/w Rule 168 of the Drugs Rules)

The Drugs Act imposes strict standards and not every ayurvedic drug can qualify as an ayurvedic drug. In certain circumstances, an ayurvedic drug can be deemed to be misbranded under the Drugs Act if the drug is so colored, coated,

powdered or polished so as to cause damage to the drug, the damage being concealed; or if the drug is made to appear of better or greater therapeutic value than it really is. (Section 33-E of the Drugs Act) Additionally, if the ayurvedic drug contains any harmful or toxic substances that may render it injurious to health; or if any substance has been mixed in it so as to reduce its quality or strength, then, in such an event the ayurvedic drug manufactured shall be deemed to be adulterated in content. (Section 33-EE of the Drugs Act)

Any company proposing to manufacture ayurvedic drugs must take adequate precautions at the time of manufacture to prevent the drug from being categorized as poisonous under the ayurvedic systems of medicine. (Schedule E of the Drugs Rules)

Chinese herb drugs face same problems

Lack of global acceptance is not unique to traditional Indian medicines only. The traditional Chinese systems of medicines based on a variety of herbal formulations too are in the boat similar to ayurveda. According to media reports, the Chinese government and companies too have started to apply modern production techniques to get US regulatory approvals.

Some 40 clinical drug trials of herb-based preparations are reportedly underway in China, Hong Kong and Taiwan currently. Huangqi is one such drug undergoing trials on human volunteers in local hospitals. This yellow-rooted plant is believed to control swelling and promote skinregeneration. Tests on rats had been completed. Dietary supplemnts such as Bak Foong pills, whose ingredients include deer antlers and ginseng, are other famous products now under modern trials.

Bak Foong pills are popular among middle-aged and menopausal Chinese women who believe these enhance the immune system, improves digestion, regulates ovarian hormones and reduces the risk of heart problems.

Chinese herbal medicines, like India's, don't have quality data to gain acceptance regulatory authorities. Most of the benefits are based on anecdotal evidence word of mouth publicity. Systematic scientific efforts to validate the properties were rare in both countries.

For global acceptance more needs to be done. Apart from scientific validation, the production plants have to get the globally accepted certification called good manufacturing practice (GMP). This certification will conform to manufactured conditions that are clean and free of contaminants.

In 2000, the Federal Drug Administration of the US (FDA) stopped imports of the Chinese herb family Aristolochia after reports of kidney failure among users in Britain and Belgium.