

Are Phytopharmaceuticals an industry in the making?

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Phytopharmaceuticals are medicinal plant-based pharma products from any part of the globe. These are very inclusive and boundry-less as compared to other traditional forms. The leads for these can have their origins in ASU, chinese medicine, Kampo medicine, Bhutanese medicine, tribal or any other sources. The interesting fact about this emerging bioscience industry is that it is being curiously watched and criticized by Ayurvedic companies. The latter fear that the phytopharma products might dilute their stakes and common people might feel that ayurvedic products lack quality. However, at the same time, the pharmaceutical industry that has almost gone defunct on serious drug discovery programs may find it exciting and eventually lap it up as an opportunity.

A little backdrop of the recent activities might help a bit. The Government of India has published a draft amendment to Drugs and Cosmetics Act, and Rules (D&C Act and Rules) on October 24, 2013. This creates regulatory provisions for defining phytopharmaceuticals (botanical-based drugs) and a schedule providing requirements of scientific data on quality, safety, and efficacy to evaluate and marketing authorization for a plant-based lead as a drug on similar lines to synthetic, chemical moieties. There also has been a meeting of the committee in June on the subject that will discuss and decide the recommendations to the government.

Currently the definition and regulatory aspects of phtopharmaceuticals are being hotly debated. What makes the situation complex are the overlapping mandates of the Department of Ayush (DoA) and Central Drugs Standard Control Organisation(CDSCO) are required to be dealt with. The underlying hope comes from the fact that there would be more credibility as far as safety and efficacy are concerned as the companies that deal with these, would also conduct proper toxicology and human clinical trials unlike the traditional forms of medicines.

Experts also place the onus on industry to put pressure on the government bodies and regulatory agencies to change certain guidelines. With plerthora of information available, there is not even any need to start from the beginning. It is important to note that there are 2400 codified plants and 3000 non-codified plants used by the tribals in India. The first ever Auyurvedic pharmacopoeia Voll was published in 1986 with 80 monographs. Though there have been many published works with fresh

monographs, none has been granted any official status so far.

Recently, the Biotechnology Industry Research Assistance Council (BIRAC) in collaboration with Clinical Development Services Agency (CDSA) organized a one day regulatory workshop on "Emerging Needs and Regulations on Phytopharmaceuticals" on June 18, 2014 at New Delhi. This was the 'Third Workshop' among the 'Regulatory Workshop Series' while the earlier two were on New Drugs and Biopharmaceuticals. The workshop brought together regulatory educators and experts from various institutes and industries. The goal of this workshop was to provide direct, relevant and valuable information on key scientific aspects of phytopharmaceuticals including its regulations in India. Its timing was welcomed by the participants and speakers who said that it was the need of the hour.

"There is no scarcity of bioresources in India," says Dr Renu Swarup, managing director, BIRAC and senior advisor, Department of Biotechnology, adding that, "Industry has a very special role and that is moving from laboratory to critical product development." All funding bodies such as Indian Council for Medical Research (ICMR), Department of Science and Technology (DST), Council for Scientific and Industrial Research (CSIR) will have to work together to shape phytopharmaceuticals. This has to be a part of our exercise to expand and move towards \$100 target."

On the contentious regulatory scenario, Dr Swarup remarked that while it is essential, it should not be a barrier. Both over-regulation and under-regulation are a barrier and a science based approach is required for product development.

"Modern medical science tried to eradicate plant ancestry but its good to see a comeback," said Dr S S Handa, former director, CSIR-Institute of Integrative Medicine (IIIM), Jammu. The renowned scientist feels that the time has come for redrawing the regulatory strategies and for removing the overlaps between the regulatory bodies.

"We require a holistic health policy. Ayurveda and allopathy can work in tandem to create new medicines that benefit a huge number of patients. Infact, there is no need to start afresh as the leads that are already available could be leveraged to produce new drugs," said eminent clinical Pharmacologist, Prof. Ranjit Roy Choudhury.

Listing out the benefits of the emerging area of phytopharmaceuticals, Dr C K Katiyar, CEO Healthcare (Technical), Emami, Kolkatta, said, "It will boost the R&D based pharma companies and bring in required change in mindset, forcing investments in research and competition leading to quality." He added, "Existing years old Ayurveda companies have not contributed much is real research and impetus is highly required despite opposition from few lobbies."