

## DRAFT AMENDMENT TO DRUGS AND COSMETICS RULES TO LICENSE SCIENCE BASED BOTANICALS, PHYTOPHARMACEUTICALS AS DRUGS IN INDIA

The Government of India has published a draft amendment to Drugs and Cosmetics Act, and Rules (D&C Act and Rules) on 24<sup>th</sup> October 2013.<sup>[1]</sup> This creates regulatory provisions of 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. In India, it is known that though the new draft regulation was not present, Guggulu tablets (for treatment of hypercholesterolemia), Ginkgo-biloba tablets (to treat temporary loss of memory), and Silymarin capsules (to treat liver disorders)<sup>[2]</sup> have been approved and marked as drugs by the Central Drugs Standards Control Organization (Drug Controller General of India). However, it is known that approval of Guggulu tablets took a more than a decade to get this approval as a drug. It had required efforts to convince the authorities that several requirements applicable to a synthetic chemical were not possible for a botanical-based product.

There is a need for development of science-based drugs from botanicals especially from the basket of traditional knowledge (namely Ayurveda), which has a long history of safety and use documented in the authoritative books. The authors are not the first people to have felt this need for separate and appropriate regulatory provisions for botanicals as drugs. In fact US Food and Drug Administration (FDA) has published a document titled “Guidance to Industry for Botanical Drugs” in June 2004.<sup>[3]</sup> It is also known that US FDA has issued a marketing authorization to a topical cream containing standardized green tea extract as a US botanical for treating genital warts after evaluating the respective Investigational New Drug Application scientifically. The authors believe that India should have had taken leadership in a similar way. Government of India appointed a committee for this purpose in August 2008.<sup>[4]</sup> The committee was chaired by Dr Nitya Anand and Dr DBA Narayana served as a convener. Prof. SS Handa, Prof. RH Singh, Dr CK Katiyar, Dr Amit Agarwal, and Dr GN Singh were the members of the expert committee.

Several eminent leaders of the pharmaceutical industry and pharmacists who delivered their annual presidential addresses to the Indian Pharmaceutical Congress, which is held annually since the last 64 years, talked about the need to develop botanical drugs from leads inspired by Ayurvedic wisdom.<sup>[5]</sup> However, in order to remove potential confusions amongst Ayurvedic fraternity about the amendments, we stress the need to recognize various aspects covered below:

1. The above draft regulations are under Chapter IV of D&C Act and Rules, and hence related to synthetic drug-based products.
2. Ayurveda, Siddha, and Unani (ASU) drugs are regulated under Chapter IVA of D&C Act and Rules, and hence, the above draft regulations do not have any impact on the way ASU product is currently regulated. Those who wish to continue to manufacture and sell ASU drugs under the current ASU licensing system of ASU preparations (as per classical texts) or proprietary Ayurvedic medicines are allowed under law can do so.
3. The above draft regulations are also not a ‘mandatory’ provision that applies to ASU drugs in any way.

At this juncture it is important to recognize the following:

1. Phytopharmaceuticals can be from a botanical (medicinal plant) from any part of the globe.
2. Phytopharmaceutical’s proposal above is in line with regulations in USA, China, and other countries involving scientific evaluation and data generation. It does not simply depend on traditional knowledge alone.
3. Phytopharmaceutical’s proposal would promote innovations and development of new drugs from botanicals in a scientific way, and would give boost to research in drug development for innovators, industry, and national laboratories and pharmaceutical research labs in India.
4. Phytopharmaceuticals as proposed above permits development as a drug under chapter IV of D&C Rules, adopting the drug development technologies involving modern techniques of solvent extraction, fractionation, potentiating steps, add-back techniques, modern extraction techniques (like CO<sub>2</sub> based extraction), freeze-drying, formulation developments, and many other techniques. Stress on high degree of characterization of the plant-based ingredient as a phytopharmaceutical is a requirement that is not generally asked for any traditional medicine (TM). Ayurvedic drugs are regulated differently and need to meet the requirements given in authoritative texts recognized in the schedule and also have to be

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processed using methods given in such texts.

5. The leads for phytopharmaceuticals can have their origin not only in TMs like ASU, Traditional Chinese Medicine, Kampo Medicine, Bhutanese Medicines or from Ethnobotany, tribal medical practices, and other such sources. Most nations are already putting regulations for access and benefit sharing in such cases and exploitation will not be going unregulated.
6. Phytopharmaceuticals would need to be mandatorily evaluated for safety (toxicology) and efficacy through well-conducted human clinical trials on lines similar to synthetic compound-based drugs. Such mandatory requirements do not apply to Ayurvedic medicines. Information on possible mechanism of action also is a requirement, not generally known or required for TMs.
7. Phytopharmaceuticals when approved by Drug Controller General of India would have the same status for marketing as that given for a synthetic compound-based drug. The committee that prepared these draft regulations approved by Drug Technical Advisory Board (DTAB)—the statutory body under the drugs law to advise the central government on technical matters relating to drug—has recommended that products licensed under these regulations may be allowed to be prescribed by both Bachelor of Medicine, Bachelor of Surgery (MBBS) and Bachelor of Ayurvedic Medicine and Surgery (BAMS) qualified physicians.

We feel that this new class of drugs would encourage introduction of extensive evaluation through biomedical sciences, therefore would help in the acceptance of and expand the use of herbal products by modern medical profession. Across the world, there is a rising interest and demand for plants as a possible source of therapeutics for unmet medical needs, and this step would bring this aspiration one step closer to reality. Upon finalization of this regulation, which we feel need to be done as soon as

possible, number of national laboratories in India, scientists groups, and industrial research and developments (R & Ds) who have been working on botanical leads can look forward to take this route for getting marketing permissions. New entrants/investors will get encouraged to invest in this route for drug development.

**DB Anantha Narayana, CK Katiyar<sup>1</sup>**

*CEO, Ayurvedic Trust, Bangalore, Karnataka, <sup>1</sup>Former Director, Herbal Research, Ranbaxy Research Centre, Gurgaon, Haryana, India*

*Address for correspondence:*

*Dr. DB Anantha Narayana, Ayurvedic Trust, Bangalore-560 085, Karnataka, India. E-mail: dba.narayana@gmail.com*

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