

Nutritionals Nutraceuticals Functional Foods Dietary Supplements

NuFFooDS

perspectives on science & business
Spectrum

Volume 3 | Issue 6 | February 2016 | ₹100

www.nffoodsspectrum.in

68 pages including cover



Need for strong hand holding

Budget 2016-17



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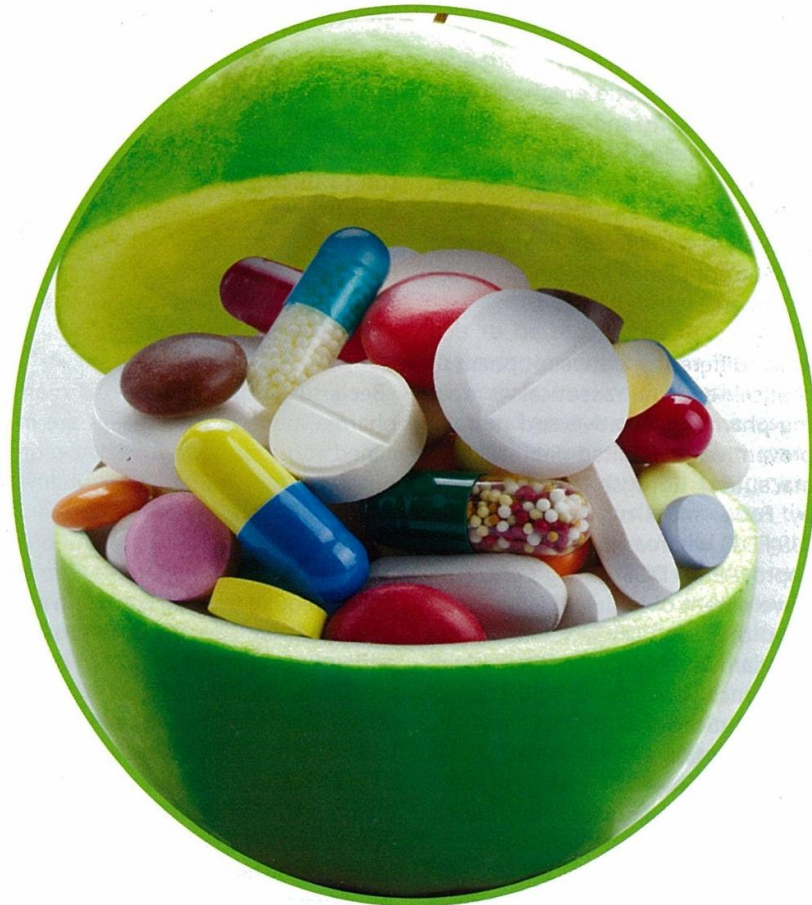
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Nutraceuticals and Pharmaceuticals

With the growing burden of diseases all over the world, there is an increase in the consumption of medicines. There is a movement from developed nations to the emerging ones. The emerging nations are experiencing a change in the demographics wherein the incidence of lifestyle diseases is on the rise. The young population is keen on adopting preventive measures and means to stay healthy and fit. Moreover, the trend indicates that the market is shifting from curative ways of treatment to preemptive and preventive ways. Both preemptive and preventive methods of treatment depend largely on nutraceutical.

A perfect example of a curative method would be microbes. Microbiome that live in the human body protect their host in lieu of food and shelter thus being a vital part of the host's wellbeing. A disruption in the microbes in the body can lead to serious health conditions ranging from obesity to diabetes, through heart disease, asthma and such lifestyle diseases.

In pharma, these microbes are treated only when they are disturbed. Pharmaceuticals have a system centric approach wherein the affected body system such as the cardiovascular system, gastrointestinal system is treated separately. Similarly, nutraceuticals have a nutrition based approach where the balance of the microbiome is always maintained in the body.



Nutraceutical does not alter microbial balance (which is required for in balance health) within body like drugs can alter. If either of the system is used separate from the other then the patient's recovery and resistance may not be as quick and effective. When a patient centric approach is adopted then both pharmaceuticals and nutraceuticals would work hand-in-hand. So, they would not only carry out their individual functions but also

aid each other for the quick recovery of the patient, instead of competing with each other.

Recently, there is a global disenchantment with drug industry for various reasons ranging from chemophobia to the industry doctor nexus. However, this general lamenting on pharma performance is not always justified. Unlike drugs, nutra industry has grown from naturals and nutritionals.



Drug industry is focused on dis-

eases, whereas nutra emphasises on wellness, health and longevity. The latter are major ingredients in the very definition of Ayurveda and traditional Chinese medicine. Obviously, safety is paramount when a large healthy population ingests any product for an extended period.

Basic difference between pharmaceutical and nutraceutical is that the pharma is curative and nutra is preventive. In United States pharmaceutical (drugs) are regulated by Food and Drug Administration (US-FDA) whereas in India drugs are approved by DCGI (Drug Controller, Government of India) which is regulated through CDSCO (Central Drug Standards and Control Organisation). Difference is mainly in regulation of nutraceuticals that it does not have any regulation authority even in USA and India. That is the biggest lucrative factor in favour of nutraceutical companies for faster production.

Although there is only one check point regarding quality control by FSSAI (Food Safety and Standards Authority of India) before launching any nutraceutical product. According to law there is no prerequisite of conducting clinical trials before nutraceutical approval in Indian market if it does not claim any health related benefit. So there is big gap in establishment of safety and efficacy data for nutraceuticals. Incorporation of clinical trial with pharma drugs takes 8 to 9 years for new molecule to come

in the market. In addition pharma companies have to spend tremendous amount of money. In comparison to that nutraceutical companies have to spend little amount of money for production in a short time span. Even matter of nutraceutical companies umpteenth profit also make in comparison of drug companies.

Because of these factors so many pharma industries nowadays are inclined to produce and market more nutraceuticals rather than pharma drugs. These unjustifiable laws and regulations allow so many irrational nutraceutical combinations which do not require treating condition and does not play any role in improving patient's condition.

There is a well-known and highly marketed product FDC and Vitamin B12 for diabetic neuropathy. There is good reason to make and improve patient's condition with this combination. But there are so many other combinations having amino acid and other vitamins also available in the market in addition of these two ingredients, safety and efficacy of which have not been established.

Other important example is Vitamin E. There is documentary proof of effectiveness of Vitamin E in a dose of 200 mg RDA which is a very good antioxidant available in the market. But in this era so many different dose strength of Vitamin E (400 mg) also available which is really very high in

dose as compared to what is required for intake. This much dose can even generate more free radicals which even further damage cell and worsen patients' condition.

Another good example is in CVS disorder. Omega 3 fatty acid plays a vital role in lowering cholesterol, but adding this with other amino acids and vitamins make this combination irrational because safety and efficacy of this is not established. Another very important example of marketing irrational combinations is of methylcobalamin preparations with variable dose strengths. Only 1500 mcg dose strength of RDA is rational in combination, rest combinations with different strengths are irrational.

Pharmaceuticals spend millions of dollars for research and paperwork for a new therapeutic claim of an established drug to satisfy Food and Drugs Administration requirements. Food and Drugs Administration requirements for health supplements are not at all stringent apart from barring them from making any false health claims about their product and adding a disclaimer.

The nutraceutical industry is not far behind offering stiff competition to pharmaceutical counterparts. But Indian government should implement few laws and regulation and to control irrational production and make nutraceutical market towards more rationality. **NS**