

# Nutra industry offers stiff competition to pharma counterparts

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**W**ITH the increasing disease burden the world over, 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. Microbiomes 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 disorientation with drug industry for various reasons ranging from chemophobia to the industry doc-

tor nexus. However, this general lamenting on pharma performance is not always justified. Unlike drugs, nutra industry has grown from naturals and nutritional. Drug industry is focused on diseases, 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 pharma is curative and another is preventive. In United States pharmaceutical (drugs) are regulated by food and drug administration (FDA) whereas in India (drugs are approved by DCGI (drug controller government of India) which is regulated through CDSCO (Central drug standards and control organization). 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.

There is no check point before coming any nutraceutical product if it is not in the Indian market. 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 for nutraceuticals. Incorporation of clinical trial with pharma drugs takes eight to nine years for coming new molecule in the market in addition pharma companies have to spend tremendous amount of money. In comparison to that nutraceutical companies have to spend only a little amount of money for production in a short time span.

Because of these factors, so many pharma companies now a days are inclined to produce and market more nutraceuticals rather than pharma drugs. These unjustifiable laws and regulations market so many irrational nutraceutical combinations which do not require treating condition and does not play any role in improving patient's condition. For example there is a well-known and highly marketed

product FDC named metformin and vitamin B12 for diabetic neuropathy which is a long term complication in case of type 2 diabetes mellitus. 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 which safety and efficacy have not been established.

Other important example is Vitamin E. There is a 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 a 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 to cell and worsen the patients' condition. Another good example 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.

Pharmaceuticals spend millions of dollars for research and paperwork for a new therapeutic claim of an established drug all to satisfy Food and Drugs Adminis-

tration 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. Indian government should implement laws and regulations to control irrational production of nutraceuticals. DCGI has to take few steps for betterment of patients and their health. ♦



*(The author is Pharmaceuticals Consultants and Editor-in-Chief of IJM Today)*



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