INTERVIEWS | INTERVIEW

"Nutraceutical industry will be suffocated to death"

The Food Safety Standards Authority of India (FSSAI) notified stringent Food Safety and Standards Rules and Regulations in 2011 under the Food Safety and Standards Act (FSSA) 2006, and made granting of licenses, renewals etc. very stringent. As vitamins,

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The Food Safety Standards Authority of India (FSSAI) notified stringent Food Safety and Standards Rules and Regulations in 2011 under the Food Safety and Standards Act (FSSA) 2006, and made granting of licenses, renewals etc. very stringent. As vitamins, dietary supplements, etc. were under the purview of FSSAI Rules 2011, many of members of Indian Drug Manufacturers' Association (IDMA) were adversely impacted. Hence for detailed follow up with concerned authorities, IDMA has formed a Nutraceuticals Sub-Committee and Dr R K Sanghavi, Consulting Clinician and Consultant - Healthcare NeuroMarketing was nominated as Chairman to work closely with the Regulatory and Medical Sub-Committees of IDMA. **In an interaction Dr R K Sanghavi shares his views on the regulatory system related to food safety as Chairman - Nutraceutical Subcommittee, IDMA.** Excerpts.

According to you, what is the current nutraceuticals market in India? What is the percentage growth rate over last year?

Indian nutraceutical market is approx $ 1,700 million (2012) and growth rate being 13%. The three major sectors of the nutraceuticals industry include Dietary supplements: 64%, Functional foods: 24% and Functional beverages: 12%

What are 10 major challenges these sectors are facing?

1. No separate rules and regulations for nutraceutical products
2. Product approval system instead of ingredient approval as is prevalent in regulated markets
3. Exhorbitant application fees for approval
4. Referral of product for Scientific Committee assessment (with additional equal fees paid extra) for simple nutraceutical ingredients which are already in market overseas, even in India since years and having ample documentation on net.
5. Product approval required for site approval
6. All operations are Delhi-based - very difficult for small & medium enterprises to co-ordinate
7. Spate of advisories - resulting in ridiculous need to change dossier already submitted (and also paying fees application again)
8. Product rejection done without scientific reasoning or permitting FBO to represent the case.

9. No revert by FSSAI to emails sent; appointments usually not given; no cell formed to address grievances.

10. RDA for nutrients imposed rather than upper tolerable limits which is the international norm.

With government of India implanting Food Safety and Standards Act 2006, how do you see the regulatory system in India related to Food Safety and Standards and its impact on the industry?

With the current style of functioning:

1. Nutraceutical industry will be suffocated to death
2. FBOs will churn out useless products (homeopathic quantities) for business continuation thus resulting in depriving patients of real benefits of alternative natural products.

Is this new system helps the industry? If yes, to what extent? Your suggestions to overcome these issues.

The new system can benefit the nutraceutical industry if:

1. Separate rules in place for proprietory foods, nutraceuticals, etc
2. Panelists include personnel who have worked in nutraceutical industry for 5-10 years and handled products (sales & marketing - not mere R&D, research)
3. Medical doctor esp with nutra background should be a guiding force rather than government officials associated with research, analysis etc. of foods.

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