

Need for cost effective substantiation of efficacy of nutritional health claims through bioavailability data for wide penetration of dietary supplements in the national health care systems

D. P. Attrey

Amity University, India

Dietary supplements (DS) are multi-billion dollar business. Their safety and efficacy is validated to ensure true label claims. No Food Business Operator (FBO) is supposed to guarantee efficacy with inadequate scientific justification. Burden of proof of scientific justification is on the FBO instead of regulator. DS differ from drugs (which are intended to diagnose, cure, mitigate, treat, or prevent a disease); both intending to affect body structure and function. Drugs have to be pre approved by FDA (after clinical validation of safety and efficacy); DS do not require prior FDA approval or pre-market testing.

Regulators need substantiated evidence of safety for which they are responsible to the public. But for making the health claims true and not misleading, documentation for efficacy has also to be generated by concerned FBO through demonstrated substantiation. Bioavailability (BA) of the product is a major tool for substantiation of efficacy. DS fall in grey area between food and drugs. Their efficacy issue, based on BA substantiation, cannot be as rigorous as for drugs and needs to be revisited for economical production of DS. It is neither understood properly by researchers nor implemented properly by industry to satisfy the regulatory requirements.

Discussion on removal of 'prevention' clause from the disease claims and incorporating it in structure and function or Disease Risk Reduction (DRR) Claims, without affecting the public interest, also appears to be the need of the day. This is likely to benefit healthcare systems as well as industry, immensely.

Biography

D.P. Attrey, a University Gold Medalist, is Convener of Sub Group of Scientific Panel on Labeling and Claims, Food Safety and Standards Authority of India (FSSAI). He has been instrumental in finalizing labeling guidelines for health claims in India. He has developed a multi vitamin herbal beverage and a memory enhancer. He is lead auditor of ISO 9001 & 22000 and is NABL expert. He has worked as Director of many Government Organizations, including Defense Institute of High Altitude Research. Published/presented > 80 papers and filed 12 patents. He has visited many countries including Russia & China.

dpattrey@amity.edu