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## Need to Curb Down Malpractices and Adulteration in Dietary Supplement Industry in India

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#### ABSTRACT

In this article, we explore the significant aspects of dietary supplements, including their uses, needs, legislation, and related case law. The dietary supplement industry in India is a multi-billion-dollar business encompassing a wide range of products, from simple vitamin tablets to powders and dry products. We will examine the challenges faced by the supplement industry, strategies to address them, and the various legislations that govern this sector, including the penalties under these laws.

We will also delve into the reasons for malpractice within the supplement business, its impact on health, and the growing health consciousness in India. Additionally, we will review various case laws that define and regulate the use of dietary supplements. The penalties under the Food Safety and Standards Authority of India (FSSAI) will also be discussed.

This article aims to provide an in-depth analysis of an expansive industry that remains under-regulated by government bodies, often perceived as a niche market rather than the global multi-billion-dollar industry it is. The government's approach to maximizing tax revenue from this industry, without recognizing the potential benefits of these products for enhancing the physical capacity of the average Indian citizen, is also critiqued. Furthermore, we argue that in India, laws related to dietary supplements are overseen by the FSSAI, a body that may lack the competence required to effectively regulate this industry.

#### I. INTRODUCTION

This topic deal with one of the important topic in our society which is effecting health of million people. As there is a boom in gym membership and health conscious people and athletes are growing in India, the use of supplement like protein powder, creatine, omega-3, BCAA, Pre workout, multi-vitamin are also getting popular among the people of India. To curb down this malpractices strict regulation of to maintain purity and standard in manufacturing those

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supplement and also strict testing of this supplement is required to check the uniformity in among the product, to insure valid testing a independent body is required which have no connection towards this company which manufacture them.

As the standard of living is increasing in India day by day and economy is also increasing at a higher pace then around the globe. The market of this supplement are also increasing day by day as they provide physical benefits to person engaging in physical activities like weightlifting, sprinting or other atheletic sports which put higher stress on muscle and cardiovascular system to recover and gain muscle from lifting 0.7g/pound or 1.5g/kg protein is needed to build muscle and increase muscle mass. Higher Muscle mass give advantage to athletes in various sports as seen in various Olympic, football games and cricket athletes having superior stamina , strength and durability then a normal person. Supplement are used to supplement the protein, vitamins and minerals which people can get from diet but due to convince use supplement to fulfill there daily needs.

Supplement are not only popular between athletes but are also popular between the common people due to being easy to use in day to day life without any side effect as it is extracted from natural source if there is no adulteration is done.

#### II. USE OF DIFFERENT DIETARY SUPPLEMENT

#### (A) Protein Powder

Protein Powder is one of the main dietary supplement that is popular between Indian youth due to its versatility and effectiveness in muscle building and stamina building in young athletes and weightlifter. Protein Powder also provide alternative to vegetarian who can't get there protein intake from meat and egg. One 30 ml scope of protein powder provide atleast 27 g protein equal to 130 g of chicken breast not only protein powder is convenient but are also within the range of meat products in case of pricing. This supplement is easy to use and convenient. Protein Powder are extracted from milk(whey, casine), pea, plant based sources, soy etc. The animo profile of milk based protein are higher then plant based protein

#### (B) Creatine

One of the most researched supplement with no side effects if taken in moderation. It can also be used to Increase muscle mass in a person as it increases the water retention in muscle which led to more muscle as muscle are primary made up of 74 % water 24% protein and rest made up of amino acids. This naturally led to strength gain and overall better athletic ability. Creatine also produced naturally by body and also present in meat and diary product vegan and

vegetarian get maximum benefit while using cretein

#### (C) Multi vitamin

Multi-vitamin talents and single vitamins tablets(like omega-3) is also very important for many people in India as various diet have deficiency of various essential vitamins and minerals in average Indian . Many multi-vitamin tablets are provided by government for the fulfillment of art 47 which states that rise in standard of living . Multi vitamin Tablets provide various benefits like less illness from any deficiency of victim . especially women have various deficiency like iron and vitamin d.

#### (D) Pre workout

Pre workout are just caffeine packed supplement with various other minerals with help to push the limit in gym or cardio session, they are sometimes caffeine contain in it brutally overdosed or underdosed.

#### **III.** LEGISLATION RELATED TO SUPPLEMENT

Most of the supplement are govern by Food safety and standards authority of India(FSSAI) fall under its preview, FSSAI regulate it distribution, manufacturing and sale of such product to I sure they meet quality standard and safety guarantee by the company who manufacture them. Supplement company are required to follow guildlines of FSSAI to obtain the necessary license and to qualify it's parameters. The FSSAI also provide punishment provision, search provision etc to maintain a fear of law among this companies. The dietry supplement are also governed with durg act.

#### (A) Punishment for adulteration in FASSI

• penalty of unsafe supplement (sec59)

A person sell or distribute any supplement that is unsafe he can be penalized with imprisonment of 6 months and fine of upto 5 lakhs

• penalty of substandard supplement (sec61)

A person manufacture for storing, sellling or distribution any substandard supplement he will be punished with 6 months of imprisonment and fine upto 3 lakhs.

#### IV. SIDE EFFECT OF SUPPLEMENT AND MALPRACTICE BY SUPPLEMENT COMPANIES

#### (A) Protein powder

Protein supplements are extensively used for muscle building, weight loss, recovery from

exercise, improving endurance & cardio-performance. Major challenge with protein supplement is undigested protein and impaired gut health which results in nausea, dehydration, diarrhea, constipation, indigestion, stomach pain, and decreased appetite. Several studies have linked plant protein with reduced metabolic syndrome incidence. Probiotics can improve gut health as well. The objective of the study is to assess the efficacy and safety of protein supplement in promoting health and wellbeing in healthy adults. The present trial is a double blind, multi-centre, randomized, placebo controlled, clinical trial involving 60 healthy individuals. The treatment duration was of 90 days. There also amino spiking done in protein powder to show higher protein content with various amino a various soy protect are also mixed with whey powder to cut the cost.

#### (B) creatine

Creatine is the safest and most well-studied sport supplement. But there are a couple of concerns surrounding its use. ItIt may cause bloating in high doses. some claim that creatine is bad for your kidneys, but this claim is not backed by scientific evidence.. may cause water retention in muscle. Various companies in cretaine manufacturing business try to use chalk powder in cretaine as method of cost cutting.

#### (C) Pre workouts

To boost energy levels and performance during exercise, many people turn to pre-workout supplements. These formulas generally consist of a flavoured mixture of several ingredients, each with a specific role in improving performance. Yet, some people experience side effects after taking them.Share on May make you feel jittery as Caffeine is one of the primary ingredients in many pre-workout supplements. This stimulant has been shown to increase muscle strength and output during exercise while In theory, caffeine allows you to get more out of a given workout , Nonetheless, caffeine has several potential , especially if you consume too much. These include insomnia, nausea, increased heart rate, headaches, anxiety, and jitteriness or restlessness (What's more, many pre-workout supplements pack high amounts — up to 500 milligrams (mg) of caffeine per serving. Serving sizes typically range from 0.35–1 oz, or 10–30 grams (g).In comparison, 1 cup, or 240 ml, of coffee contains only 95 mg .

The best way to reduce side effects is to start with a small dose of a caffeinated pre-workout supplement, slowly increasing your dosage to see what you can tolerate , it's best to avoid caffeine for at least 6 hours before bed to help prevent sleeplessness.

Of course, you can also choose pre-workout supplements without any caffeine.

Sometimes the caffeine content in this pre workout are overdosed to some extent which can led

to heart failure and caffeine addiction.

#### V. CHALLENGE TO TACKLE RELATED TO SUPPLEMENT

#### (A) Wide range

The scope of dietary supplement is very wide and to differentiate between them need a knowledge about them , how do those supplement work , how to use them , how to detect adulteration in them is very limited to selective person.

#### (B) Lack of knowledge

The knowledge related to dietary supplements are very niche and only person related to bodybuilding or athletic can only identify and prescribed them to people. Even many dietary doctor in India are unaware of the many of the dietary supplements and it's function and usage due to this many people are suffering from side effect due to overdose of this supplement. People like beginner athletes and weightlifter are the onces who generally overdose the uses of this product

#### (C) Lack of medical practitioner related to supplement

The lack of medical practitioner related to dietary supplement who can guide increasing athletes and weightlifter India has caused a wide spread disparity among a legit medical practitioner who have knowledge related to dietary supplements and among people who use this supplement and are unable to contact them due to various reason like this type of experts are low in no with respect to people who use them

#### (D) Blatant Adulteration in supplement market

The various supplement in India and foreign are famous for malpractice and adulteration in dietary supplements to tackle the growing demand and keeping price low like in case of protein powder amino spiking and sugar mixing is done with whey to increase taste and reduce cost. The lower costing product in perform better in Indian market as the middle class Indian person try to find budget friendly option for them.

#### (E) Lack of specified legislation

The dietary supplement are governed with FASSI rather than specific legislation which can used to tackle as this problem can be solved by providing a new search agency which are neutral and check the requirements are meets or not. Many dietary product are made from dairy products to insure that the quality is meet the cows from which milk is extracted should also be checked and protected from abuse that happen in dairy farming industry to get superior supplement and also chemical that are manufactured should be checked to insure compliance of company related to people who creatine, BCAA etc.

#### VI. HOW TO TACKLE THESE CHALLENGES

• Amendment In Definition of FASSI

Amendment in FASSI is needed to tackle the adulteration of dietary supplements in the FASSI by expanding the definition to get understanding of the type of supplement it's use and misuse, there also a need to include the type of adulteration that can happen in this type of supplement by the supplement company to understand and implement necessary steps

• Increase in punishment

As the adulteration of supplement can led to various heart, body and mental health problems it punishment should be enhanced from simple imprisonment of 6 months and fine upto 5 lakhs to 3- 5 years and fine upto 50 lakhs to curb down the this adulteration industry that exist within the supplement industry to maximise profit at the expense of people life

• Tax cuts to improve supplement industry

The supplement industry is heavily tax up to 18% by the central government under Central goods and services tax which most of the time promote the adulteration of the supplement by the company because of high manufacturing and low profit industry with high tax imposed upon them lead to cost cutting and malpractice to secure profits from this product.

• Promote education related to these supplement in medical field

With the study and education related to supplement are added in slybuss of medical practitioner will yeild a great result to tackle this problem in education common people about the safe dosage how to use supplement etc.

• Separate Independent agency for testing

There is also need of independent agency for testing other then the testing done by the factory on themselves as the independent agency provide superior testing results and insure compliance of FASSI guild lines

#### VII. CASE LAWS IN INDIA RELATED TO SUPPLEMENT

• Case: re Windlas biodas Ltd

This product has to be judged entirely in the light of the words in tariff and not with reference to the licence under the Drug Control Act.

• Case:cadila pharmaceutical Ltd v state of Kerala

In this case Dietary Supplements falls within the definition of "drug" requiring licence under ... branded formulations, generic and oncocare products, animal health and natural products, dietary supplements, biotech products, chemicals, etc.

• Case: narendra sahi v state of Jharkhand

Protein Powder was being sold as dietary supplement under the license granted under the Prevention of Food Adulteration Act though the active ... though the capsules were the 'Drug' and not the as Vitamins in particular therapeutic range is prescribed by a Doctor

• Case: sun farma laboratories limited v Glenmark laboratories

In this case definition of supplement was explained which Supplement for Medical Use, Dietary Supplements for Humans, Nutritional Supplements, Nutraceutical Preparations for Therapeutic or Medical Purposes, Nutraceuticals for use as Dietary Supplements, Pharmaceutical Preparations for Inhalers ... Medical Use, Dietary Supplements for Humans, Nutritional Supplements, Nutraceutical Preparations for Therapeutic or Medical Purposes, Nutraceuticals for use as Dietary Supplements, Pharmaceutical Preparations for Inhalers

• Case: boxobee Inc v trustrade foods

In this case it talks about the dietary supplements in hospital supplies, over the counter drugs, groceries and other herbal and dietary supplements and has its principle place of business in the afore mentioned address ... hospital supplies, over the counter drugs, groceries and other herbal and dietary supplements and has its principle place of business in the address .

#### VIII. CONCLUSION

In this era of health conscious India this dietary supplement product demands are increasing day by day and various Indian companies are also trying there luck in this business superior dietary supplement also provide superior psychical and mental capacity among the common citizen of India . The dietary supplement are kept In drugs act to extract maximum gst from them and also government is not very keen on promoting this supplement as it is seen in the bad light but if the government try to remove or minimise tax in this dietary supplement it will lead to better quality in supplement as adulteration in this industry is done to cut the cost. With India growing as a market for young people we can produce more athletes and more Olympic level athletes by providing superior quality protein powder for our teenager population and not just some sugary drinks which are sold in market with false labelling of enhancing physical and mental quality of the child in its growing days.