Available online on 15 Sep, 2024 at https://ijdra.com/index.php/journal
International Journal of Drug Regulatory Affairs
Published by Diva Enterprises Pvt. Ltd., New Delhi
Associated with RAPS & Delhi Pharmaceutical Sciences & Research University

Review Article

Open Access

Medical Foods for the management of Chronic Illness and their Regulations in India, US and European Union

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Abstract

As many chronic illnesses are incurable and require repeated treatments, this problem contributes to long-term drug use. But when it comes to managing and treating chronic illnesses, medical foods can provide an alternative to natural medications. Medical foods are foods that have been particularly prepared to meet the unique dietary needs of people with specific illnesses. When it comes to therapeutic applications such as deglutition, dyspepsia, or eating disorders, they are crucial in providing patients with nutritional support. In addition, they significantly improve patients' quality of life by lowering drug use, averting problems that could result from an excessive reliance on pharmaceuticals, and saving treatment costs. Depending on the illness, medical foods' nutritional content can be adjusted and customized. They are exempt from laws pertaining to drugs since they are not drugs. Every medical food is created especially for the chronic condition in question. As a result, the purpose of this review is to clarify the use of medical foods for conditions such as Parkinson's, Alzheimer's, anxiety and sleep disorders, pain syndrome, cancer, congenital metabolic disorders, and diabetes mellitus, and to suggest their use as a dietary supplement for these long-term illnesses.

Keywords: Foods for specific medical purposes (FSMPs); Medical foods; Chronic diseases; Congenital metabolic disorders (CMDs); regulations; FDA; Food Safety and Standards Authority of India (FSSAI); Nutrition Labeling; European Food Safety Authority (EFSA)

Article Info: Received 18 Jun 2024; Review Completed 04 Aug 2024; Accepted 14 Sep 2024

Cite this article as:
Saxena T, Yadala S, Sri AK, Reddy PM, Nijhawan M. Medical Foods for the management of Chronic Illness and their Regulations in India, US and European Union. Int. J. Drug Reg. Affairs [Internet]. 2024 Sep15 [cited 2024 Sep 15]; 12(3):13-22. Available from:
http://ijdra.com/index.php/journal/article/view/684

DOI: https://doi.org/10.22270/ijdra.v12i3.684
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1. Introduction

Foods for specific medical purposes, or FSMPs, are also frequently utilized by healthcare practitioners. They are referred to as medical foods in certain non-EU countries (such as the US and Argentina) or as enteral nutrition in other countries (such as Brazil). FSMPs are specifically prepared and processed foods meant to be used by patients under medical supervision for the dietary treatment of diseases, disorders, or medical conditions. FSMPs have been used in practice for many years throughout the past few decades, providing a solid basis for patient care related to nutrition.

FSMPs can be a patient's only source of nutrition for brief or long periods of time, or they can be given as an oral nutritional supplement (ONS) or as a supplement to the patient's usual diet by tube feeding. FSMPs are gaining popularity because of their potential to help manage health and disease. They are supposed to comply with good manufacturing practice (GMP) and general food laws. They also have to be safe for the purpose for which they are intended, make accurate claims, and be compliant with laws pertaining to packaging, novel foods, contaminants, and additives, among other things. FSMPs, often referred to as medical foods in the US, Codex Alimentarius-compliant foods in the EU, and most other countries, are broadly described as a class of foods that are prepared, processed, and presented in a way that is specifically intended to manage a patient's diet while under medical supervision. (1)

Patients who are interested in using this type of material should speak with their own physician and ensure that they, the physician, and the family understand the appropriate use, realistic treatment expectations, and potential adverse effects. A medical food's distinguishing feature is that it is meant to be used under the regular care of a physician. It's vital to remember that the FDA does not demand the same extensive testing for medical food approval as it does for prescription medication, before talking about the items that are currently on the market. While medical foods and, to a lesser extent, supplements can improve patient care when used in conjunction with pharmaceutical treatments under a doctor's supervision, they cannot replace prescription pharmaceuticals. (2)

1.1 Distinguishing Drugs from Medical Foods

While they play a significant role in enteral nutrition, medical foods are not classified as Drugs. Medical foods added to enteral nourishment can lessen the negative effects of long-term drug use, the frequency of certain complications, the length of hospital stay, and the financial losses brought on by illness. When contemplating the long-term health effects of prescription pharmaceuticals continually used by patients for the treatment of chronic disorders, healthcare providers do not want the depletion of specific nutrients.

Examples of loss of nutrients include vitamin B12 shortage brought on by using an oral hypoglycaemic drug, coenzyme Q10 deficit brought on by using statins, and vitamin B, calcium, and magnesium deficiencies brought on by often using antibiotics. Some instances of nutritional loss brought on by drug use include the frequent use of antibiotics. As a result, it is believed that using medical food and dietary supplements will effectively prevent drug-related nutritional deficits.

FDA regulations and requirements for pharmaceuticals do not apply to medical foods. Medical foods must, however, adhere to all FDA regulations established for functional and conventional foods, including good manufacturing procedures. It's a common misconception that patients can only receive medical foods by prescription; nevertheless, unlike medicinal medications, medical foods can be delivered over-the-counter. The word "Rx" cannot be found on the label of a medical food product; it is only allowed on prescription medications.

Furthermore, medical foods made for dietary control must to include labels indicating that they are tailored to the particular patient or illness and satisfy the dietary needs required to manage that condition. Every component used in the creation of medicinal meals must adhere to FDA regulations and be widely accepted as safe (GRAS). The criteria for nutritional content and health claims do not apply to medical foods. (3)

Table 1. Comparison of FDA-Approved Drugs to Medical Foods. (3,4)

Product Class Characteristic	Medical Food	Approved Drugs
Regulatory governance	Orphan Drug Act (amendments, 1988)	The FDA Modernization Act of 1997 revised the Federal Food, Drug, and Cosmetic Act of 1938.
Target audience	Patients suffering from long-term illnesses	Patients suffering from long-term illnesses
Use	Management of long-term conditions or illnesses	Management, reduction, or cure of long-term disorders or illnesses
Clinical & Scientific Data	Required to demonstrate Use	Required to prove use
Safety	Must be generally recognized as safe by panel of experts	Investigation in phases 1, 2, and 3 is required to demonstrate safety.
Efficacy	It requires clinical trials to validate use	must undergo phase 2 and phase 3 clinical testing to demonstrate safety.
Ingredients	Nutritional, not in ordinary diet	Mostly synthetic, can be nutritional
Product basis	Dietary need - metabolic imbalance can be restored by special nutrients	Safe & effective for disease & patient population
Safety standard	GRAS (generally regarded as safe) food ingredients are considered safe for consumption by the general public	authorized through an ANDA, NDA.
Scientific requirements	Recognized science - follows good scientific practices, accepted in clinical practice or peer review	Preclinical & clinical phases I, II, III
Physician supervision	Required	Required if prescription drug
Dosing	Oral or enteral	Any
Distribution	Retail pharmacy and hospitals	Retail pharmacy and hospitals
FDA-approved or -regulated	Regulated	Approved

1.2 Fundamentals of Medical Food and the Laws Governing it in various Regions

Originally, these specialized medical foods, or FSMPs, were regulated by drug laws as there hasn't been a sophisticated regulatory framework since the 1960s. But over the last few decades, they have come to be defined more and more by global food laws. An FSMP is designed to provide exclusive or partial feeding to patients who have specific medically determined nutrient requirements and whose dietary management cannot be met solely by modifying their usual diet, these patients may also have limited or impaired capacity to take, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients contained therein. (1)

2. Regulation of Medical Foods in India

Food Safety and Standards Authority of India (FSSAI) oversees the regulation of medical foods in India. Medical foods are categorized by Indian rules as "Food for Special Dietary Uses" or "Foods for Special Medical Purposes" (FSMPs), which are used to manage specific medical disorders through dietary means. The majority of FSMP formulations are composed of one or more purified and well-characterized components from a botanical source or a synthetic molecule with pharmacological activity, and are formulated in tablets, capsules, or liquid form. FSMP is a dietary formulation designed to fulfil the nutritional needs of people with diseases or disorders through food unlike drugs. However, due to technological restrictions in the size/volume of the formats (tablets, capsules), these products may not always fit the nutritionally complete or nutritionally inadequate category of FSMP.

The FSSAI (Food Safety and Standards Authority of India) defines Foods for Special Medical Purpose (FSMP) as “Specially formulated and processed products intended for the dietary management of patients or individuals who have limited or impaired capacity to consume, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or who have other medically-determined nutrient requirements that cannot be met by normal dietary intake alone.”

2.1 Guidelines on FSMP

- FSMPs must be used as directed by a medical practitioner, with the disease, disorder, or medical condition clearly indicated.
- FSMP products should be either nutritionally complete with a standard nutrient formulation, nutritionally complete with a nutrient-adopted formulation, or nutritionally incomplete with either a standard or nutrient-adapted formulation.
- FSMP formulations should include essential nutrients such as carbohydrates /proteins/ fats/vitamins/minerals/amino acids, as well as other nutrients, to provide nutritional benefits to the consumers, and they can tailor the formulation to the target audience's medical condition, disease, or disorder.
- FSMP products may contain nutrients in excess of the Recommended Daily Allowance (RDA), but not exceeding the limits for vitamins and minerals stated in Schedule III of the Nutraceutical Regulations.

2.2 Labelling requirements:

The FSMP products' labels must include information such as "FOR THE dietary management of ___" and "RECOMMENDED TO BE USED UNDER MEDICAL ADVICE ONLY" (referring to the particular disease, disorder, or medical condition for which the product is intended and has been proved to be effective). The FBO bears the obligation of guaranteeing that a combination of substances does not interact in a way that could negatively affect its stability, bioavailability, safety, or efficacy. Combinations like this should be avoided as they may otherwise work against the product's intended functionality. (5)

In order to differentiate between the various product categories covered by nutraceutical legislation, the following table has been created (5)

Table 2. Medical foods and its parameters

S.No.	Parameters	Medical food use
1.	Description	Foods designated for Special Medical Purpose (FSMP) are those meant for the exclusive or partial feeding of individuals whose ability to digest, absorb, or metabolize regular food items is restricted, and whose dietary needs cannot be satisfied by regular foods.
2	Age group	Relevant for a minimum of two years and above.
3	Target population	Individuals with certain diseases, disorders, or medical conditions that impair their ability to digest, absorb, or metabolize common foods and whose dietary needs cannot be addressed only by changing their usual diet, consuming foods designed for particular nutritional purposes, or a combination of these.
4	Intended use	Designed to the intended audience (individuals with various medical diagnoses) in order to offer nutritional support. It might be a: 1. Nutritionally complete formulation 2. Nutritionally Incomplete formulation
5	Direction of use	to be administered orally or by tube feeding under the strict guidance of a physician
6	Duration of use	utilized for the specified amount of time as directed by a physician or clinical dietitian
7	Format/Matrix	food pattern. Currently, liquid and powder dose forms are most often used because other formats aren't appropriate for supplying the necessary dietary elements.

8	Does the product to be taken under medical advice	Yes
9	Is claim regarding health function is allowed?	No
10	Can the labelling presentation and advertisement mention that this product has the property of preventing, treating, or curing a human disease, or refer to such properties	No
11	Level of nutrients allowed	may exceed one RDA; nonetheless, it must adhere to Schedule III of the standards governing nutraceuticals.
12	Formulations containing mere combination of vitamins and minerals in tablets, capsules, syrup formats	No
13	Formulations made on single vitamin and mineral	No
14	Formulations made on single bioactive based products in tablet, capsule or liquid	No
15	Can the formulation contain hormones or steroids or psychotropic ingredients	No
16	Ingredient Schedules applicable	I, II, IV, enzymes listed in VI, VII, VIII
17	Additive Schedules applicable	VC, VD (weight reduction products), VE, VF (only for Tablets/capsules/syrups)

2.3 Classification of medical foods according to India

a) **Nutritionally complete food with standard nutrient formulation**

Enteral formulas for gastroenterological conditions; food specifically prepared for weight reduction and intended to replace an entire diet; people suffering or recovering from serious illnesses, such as stroke patients or patients recovering from severe food allergies; and patients recovering from trauma, infection, and surgery.

b) **Nutritionally complete food with nutrient adopted formulation**

Specialized dietary formulas for people with long-term metabolic conditions, such as those with fatty acid metabolism, food allergies, kidney disease, gastrointestinal issues, malabsorption conditions involving MCT (medium chain triglycerides), patients with inflammatory bowel disease, etc.

c) **Nutritionally incomplete food with standard nutrient formulation or a nutrient adopted formulation**

For individuals suffering from kidney illness, GIT diseases, acute metabolic disorders, protein replacement for metabolic conditions, etc

3. Regulation of Medical Foods in US

Medical foods in the United States are regulated by the Food and Drug Administration (FDA). Medical foods are defined as a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the dietary management of a specific disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. (21 CFR 101.9(j) (8)).

Medical foods were mostly recipes for treating people with hereditary metabolic disorders until 1972. Mostly, they were orphan goods intended for little markets. Since they were regulated as medications, their usage was required to be under medical supervision. To aid in their development and accessibility, the FDA changed the classification of these products from pharmaceuticals to foods for special dietary use in 1972. Many products that fall under the category of "medical foods" have been produced in the years in between.

Foods as specified by the Act are considered medical foods and are governed by the Act's broad requirements for food safety and labeling. For information on an exception from NLEA labeling requirements for medical foods, see 101.9(j) (8).

FDA narrowly defines the conditions under which a medical food may be marketed:

a) It must be a product that has been specially prepared and processed (as opposed to a naturally occurring food utilized in its natural state) for the patient's partial or exclusive oral intake or enteral feeding via a tube;

b) It must be designed for the dietary management of a patient whose capacity to ingest, digest, absorb, or metabolize common foodstuffs or specific nutrients is limited or impaired due to therapeutic or long-term medical needs, or who has other specific nutrient requirements that can't be met by modifying the regular diet alone;

c) It must only be intended for a patient receiving active and ongoing medical supervision where the patient requires medical care on a regular basis for, among other things, instructions on how to use the medical food.

d) It must provide nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease

or condition, as determined by medical evaluation.

e) It must be intended to be used under medical supervision.

The Nutrition Labeling and Education Act of 1990 exempts medical foods from the labeling requirements for health claims and nutrient content claims, which could be advantageous for marketing medical food products. (6)

3.1 History of Medical Foods in US

It took the Federal Food, Drug, and Cosmetic Act (FDCA) 50 years to pass before the Food and Drug Administration (FDA) could properly define "medical foods."
Because of their ability to lessen severe side effects from illnesses, what are today known as medical foods were controlled as prescription medications under section 201(g)(1)(B) of the FDCA before 1972. Manufacturers of medical foods have to comply with strict regulations in order to commercialize new products, including conducting full drug studies and submitting applications for licenses to investigate new drugs and new drug applications. incredibly expensive and time-consuming.

The FDA re-evaluated its stance on medical foods in 1972. The government took this move because it wanted to encourage innovation in the creation of medicinal foods and make sure that the general public could purchase them at a fair price.
Nonetheless, the agency continued to work toward distinguishing medical foods from meals for general consumption due to safety concerns. For instance, the FDA reasoned that Lofenalac, an infant product intended for use in the dietary treatment of phenylketonuria (PKU), a rare hereditary disorder, would be dangerous for healthy infants because it would not provide them with enough nourishment.

Consequently, enterally administered medical foods were reclassified by the agency as "foods for special dietary use," but injectable medical foods continued to be categorized as pharmaceuticals under the FDA's Drug Efficacy Study (DESI) program. In summary, parenteral nutrition—that is, nutrition that is injected into the body—retained its medication classification whereas enterally supplied nutrition was moved to the food category. Only a year later, the government exempted some food kinds intended for special dietary usage from the requirement that nutrition labels be included on select goods. Finally, Section 5b of the Orphan Drug Act, or the Orphan Drug Amendments of 1988, established a statutory definition of medicinal foods.

The Nutrition Labeling and Education Act of 1990 (NLEA) was approved by Congress and signed into law by President George H. Bush on November 8, 1990.
The FDA released updated guidelines in 2007 that further clarified the definition of the medicinal food category. (6)

3.2 FDA Classification of Medical Foods

FDA classified Medical Foods into the following categories:

a) Nutritionally complete formulas

b) Nutritionally incomplete formulas, including individual "modular" type products that may be mixed with other products before use

c) Formulas for metabolic (genetic) disorders in patients over 12 months of age; or

d) Oral rehydration products. (7)

4. Regulation of Medical Foods in Europe

Regarding hazards associated with food, independent scientific advice is provided by the European Food Safety Authority (EFSA).

EFSA provides guidance on current and potential food hazards. This guidance helps shield consumers from hazards in the food chain by informing European laws, regulations, and policymaking. Its purview includes: plant protection; plant health; animal health and welfare; nutrition; food and feed safety.

4.1 Food for Special Medical Purposes

Definition: Regulation (EU) 609/2013 defines “food for special medical purposes” as “*food specially processed or formulated and intended for the **dietary management** of patients, including infants, to be **used under medical supervision**. It is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by **modification of the normal diet alone**”*(8)

As per the Commission Directive 1999/21/EC, which was adopted under the previous legislative framework of Directive 2009/39/EC, the composition and labelling of foods intended for the dietary management (under medical supervision) of individuals suffering from specific diseases, disorders, or medical conditions must comply with certain rules. These meals are meant to be fed exclusively to those whose typical diets are unable to meet their nutritional needs, or in part. The 1999/21/EC Directive establishes minimum and maximum amounts of vitamins and minerals, as well as basic conditions for their composition.

It is effective as of February 22, 2019, with the exception of food created for particular medical uses for newborns, which is effective as of February 22, 2020.

Requires the Commission to replace Directive 1999/21/EC with specific compositional and labeling guidelines for foods intended for particular medicinal reasons through a delegated act. Regulation (EU) 2016/128, which was delegated by the Commission, was approved on September 25, 2015, and it will go into effect on February 22, 2019. The provisions of Directive 1999/21/EC are still in effect till that time. (8)

The new delegated Regulation:

- Preserves the current regulations of Directive 1999/21/EC, making minor modifications to the labeling specifications to guarantee conformity with the horizontal guidelines of Regulation (EU) No 1169/2011 for the dissemination of food

information to consumers, considering product specifics.

- Introduces the ban on food manufacturers making nutritional and health claims for specific medical uses in order to maintain legal clarity and prevent improper product promotion.
- All regulations pertaining to labeling, presentation, advertising, and marketing that are applicable to infant formulas for healthy infants and do not conflict with the products' intended use are also extended to foods for special medical purposes meant for newborns. This will guarantee uniformity among EU regulations and help prevent product misclassification.
- It also extends the rules on pesticides to foods for special medical purposes intended for infants and young children. (8)

Food intended for specific medicinal purposes: must meet this requirement in order to be sold; it falls into one of three categories:

- Food that is nutritionally complete and has a standard nutrient formulation; this food can serve as a partial replacement or supplement, or it can be the only source of nourishment;
- Food that is nutritionally full and has been specially formulated with nutrients to address a certain disease, disorder, or medical condition; this food can serve as the only source of nourishment or be used in part as a supplement or replacement;
- Foods that are inadequate in nutrients and should not be the only source of nutrition. (9)

4.2 Labeling of food information

According to Regulation (EU) No 1169/2011 on the labelling of foodstuffs, food intended for specific medical purposes must be labelled with the following statements or cautions (the first four points accompanied by the words "important notice" or equivalent):

a) whether the product is meant for a particular age group;

b) whether it can be used as the only source of nutrition;

c) whether it needs to be used under medical supervision;

d) if using the product by someone who does not have the ailment for which it is meant puts them at risk for health problems;

e) Precautions and contraindications;

f) a description of the product's usefulness in relation to the disease, disorder, or medical condition, including information on the unique processing and formulation, the nutrients, and the product rationale; the statement "For the dietary management of (the disease, disorder, or medical condition for which the product is intended)";

g) a notice stating that the product should only be used orally;

h) directions for opening the product and handling, storing, and using it.

4.3 Nutritional statement

- The amount (where appropriate) of minerals, vitamins, protein (including its source and type), carbohydrates, fat, and other nutrients, as well as their components, must be included in the required nutrition statement, with a few specific exceptions.
- Foodstuffs used for specific medical purposes are not allowed to make nutritional or health claims.

Specific requirements for food for special medical purposes developed for infants:

- Necessary information needs to be provided in a language that is simple for customers to understand.
- The labelling of products may not contain images of newborns or any other images or text that could idealize the use of the product, unless it has visuals that make identification simple or demonstrate preparation techniques
- Advertising must be limited to journals that specialize in baby care and scientific publications;
- Labeling must be created so that consumers can easily distinguish between such items and infant formula.
- Manufacturers and distributors are prohibited from directly offering free or inexpensive products, samples, or any other promotional gifts to the general public, pregnant women, mothers, or family members.
- Point-of-sale advertising, free samples, or any other promotional device must not be directed towards the consumer at the retail level. (10)

4.4 Classification of Medical Foods in EU

The three categories in which FSMP can be categorized are listed in Article 2(1) of Delegated Regulation (EU) 2016/128 in order to give an idea of the various kinds of FSMP that may exist:

a) **Nutritionally complete food with a standard nutrient:** these goods, when consumed in sufficient amounts, offer all the nutrients a patient needs at the right amounts, making them suitable to serve as their only source of nourishment. This amount will vary depending on the patient's age, body weight, and health status, among other factors, as advised by a medical practitioner. They can be taken orally or through an enteral tube as the only source of nourishment, substituting the whole diet. Depending on the patient's dietary requirements and the advice of

the medical practitioner, they may also be utilized for partial feeding.

b) **Nutritionally complete food with a nutrient-adapted formulation specific for a disease, disorder or medical condition:** Food that is nutritionally complete and has been specially formulated with nutrients to address a particular disease, disorder, or medical condition are designed to address the unique nutritional requirements that come with a particular disease or range of diseases, disorders, or medical conditions. When consumed in adequate amounts, they can serve as a patient's only source of sustenance since they contain all the essential elements at the right amounts. In compliance with the healthcare provider's advice, they can also be utilized for the patient's partial feeding. This group includes, for instance, FSMP, which was created to meet the nutritional needs of newborns with certain illnesses or ailments for whom nursing (or the use of formula for healthy babies) is not advised.

c) **Nutritionally incomplete food with a standard formulation or a nutrient-adapted formulation tailored to a disease, disorder, or medical condition:** these products are unsuitable to be used as the only source of nutrition because they either lack certain essential nutrients or contain them in amounts or balances that make them unsuitable. In addition to regular meals, an adjusted diet, additional FSMP products, or parenteral nutrition, the patient uses them for partial feeding. (11)

5. Treatment of various diseases with medical foods

Many chronic illnesses can be effectively managed with minor dietary adjustments. We will focus on neurological diseases (Parkinson's and Alzheimer's), anxiety and sleep disorders, pain syndromes, cancer, congenital metabolic disorders, and diabetes mellitus in this narrative overview. These are widespread chronic illnesses that have been shown to be effectively treated with diet and medicinal foods.

5.1 Neurodegenerative Diseases

a) Alzheimer's disease (AD)

The most frequent cause of dementia globally is Alzheimer's disease, and becoming older is the biggest risk factor. The main goals of current therapies are to address clinical symptoms and encourage normal brain aging. A smart eating pattern may slow cognitive decline and lower the risk of Alzheimer's disease (AD) and related dementias. Nutrition is a significant risk factor for Alzheimer's disease. Dietary approaches to stop hypertension (DASH), low-fat, and Mediterranean diets are examples of healthy diets that have neuroprotective effects by lowering inflammation, oxidative stress, and Aβ peptide buildup. Medical meals like Souvenaid and Axona have showed promise in treating Alzheimer's disease, but more extensive clinical trials with reliable assessment instruments are required to confirm their effectiveness, Different dietary approach can reduce AD symptoms and meet the requirements to be approved as medicinal foods. (12-16)

b) Parkinson's disease (PD)

Parkinson's disease (PD) is a brain disease that causes ataxia, balance problems, and involuntary movements due to the death of dopaminergic neurons. Age is the most important component, although there are other environmental and genetic factors that also affect it. As we age, the brain is vulnerable to oxidative stress, which is thought to be a major factor in the dopaminergic system's malfunction. In people with Parkinson's disease (PD), Lewy bodies, or α-synuclein proteins, build up in the central, autonomic, and peripheral nervous systems, causing nerve cells and intercellular connections to be destroyed. Drugs that stimulate dopamine receptors or raise dopamine levels are used to treat Parkinson's disease (PD), while there is no permanent cure. Consuming foods high in omega-3 polyunsaturated fatty acids, vegetables, seeds, nuts, xanthophylls, xanthine, and lutein are risk factors related to nutrition. A diet high in olive oil, whole grains, fruits, vegetables, seafood, dairy products, wine, and red meat items is known as a ketogenic diet (KD). The KD improves gut microbiota, decreases α-synuclein aggregation and early neuronal degeneration, and lowers oxidative stress, C-reactive protein, fasting insulin, adiponectin levels, and neuroinflammation. (12)

5.2 Anxiety & Sleep Disorder

Sleep has been associated with learning, memory, and emotional state and is essential for the human body to function normally. A disease or a sign of another mental ailment, such anxiety, can cause sleep difficulties. There is a connection between anxiety and sleep disturbances; those who experience anxiety frequently or chronically have trouble sleeping. Sleep is regulated by neurotransmitters like acetylcholine and serotonin. On the other hand, lethargy, depression, and dysmnesia are adverse effects of medications used to treat anxiety and sleep disorders. To combat these problems, medical diets that boost amino acid intake and neurotransmitter release by incorporating precursors of serotonin and acetylcholine have been developed. Research has demonstrated that these foods can shorten the time it takes to fall asleep and enhance the quality of sleep, which lessens morning tiredness. The development of GABADone, a medicinal food made of an amino acid mixture. Research has shown that medicinal food production improves the quantity and quality of sleep while reducing sleep latency. All things considered, research in the literature demonstrates that certain amino acids have an impact on sleep cycles and, consequently, central nervous system functions, such as anxiety and depression. (12,17)

5.3 Pain Syndrome

The cause of chronic pain syndrome is unknown, however symptoms typically last for more than six months or reoccur frequently. It might not be brought on by damaged tissue, but rather by sensitive tissues surrounding the spine and pain memories in the brain. Depending on the kind and location of the pain, several treatment approaches are used, although medicine is typically advised. It is ideal to employ multidisciplinary techniques,

such as manual therapy, physical therapy, aqua therapy, occupational therapy, psychotherapy, and novel therapies. In this multidisciplinary approach, nutrition and medical foods are critical components. Certain amino acids and neurotransmitters are included in medical food like Percura and Trepadone to help lessen the symptoms of chronic pain syndrome. Patients with peripheral neuropathy have reported less pain and numbness when using Percura, whereas Trepadone increases the release of neurotransmitters such as glutamate, histamine, GABA, nitric oxide, and serotonin. More research is necessary because the usefulness of these meals on chronic pain has not been well studied. (12,18,19)

5.4 Cancer

Cancer is a medical condition where cells proliferate out of control, which causes anorexia and weight loss. Twenty to forty percent of cancer-related deaths are directly related to nutrition. Myolysis is the main nutritional issue that enteral nutrition therapy addresses and is therefore essential to the treatment of cancer. ProtiMedic Amino Plus and other protein-enriched prescription diets can help cancer patients gain more muscle mass and experience fewer muscle loss. Antioxidants, immunomodulatory drugs, and antioxidants are all present in medical meals made for cancer patients to help stop the growth and spread of cancer. (12,20-23)

6. Medical Foods for Congenital Metabolic Diseases

Congenital metabolic disorders (CMDs) are hereditary conditions caused by abnormalities in certain enzymes that impact the metabolism of fat, protein, or carbohydrates. Organ transplantation and gene therapy are available treatment options, but their application is complicated by immune rejection, donor shortages, and early gene therapy. Medical foods designed especially for CMD can limit the intake and accumulation of the relevant reaction substrate, which can help lessen symptoms and their incidence. PKU, a frequent CMD, is a condition of amino acid metabolism that needs to be treated with nutrition. Medical foods fall into two categories: foods that are low in protein but still include all other nutrients, and foods that have been modified to be low in protein. Children with PKU can benefit from medical diets that have reduced phenylalanine formulations. lactose intolerance is a condition where lactose is not adequately digested; medical foods are used to treat this illness as well. Medical meals are also used to treat lactose intolerance and premature newborns. (12,24-27)

Table 3. Examples of various marketed medical foods used in treatment of various chronic diseases

Medical Food	Intended action	Reference
ALZHEIMER		
Axona	Provides the brain a substitute energy source for glucose that it can use to maintain the development and operation of synapses in the brain	(13)
Souvenaid.	The ingredients in Souvenaid effectively facilitate the formation of synapses between cell membranes	(14)
Prevagen.	A naturally occuring photoprotein from jellyfish called Apoaequorin enhances cognitive function, thinking speed, and memory.	(15)
Cerefolin	L-methylfolate, an activated form of folate, influences memory and safeguards cognitive health	(16)
CANCER		
Nutrisource® Fiber	It can be combined with pudding, yoghurt, juices, and other drinks. It guarantees soluble fiber to support intestinal health	(20)
Boost® Nutritional Pudding.	It is produced to provide 230 nutrients to energy in order to help food be converted into energy. It is free of artificial sweeteners	(21)
Medtrition ProSource.	The product can be taken orally or by tube, and it is devoid of lactose, gluten, and contains 10 grams of protein.	(22)
Impact Advanced Recovery®	This product may speed up post-operative recovery for patients and protect against the adverse effects of malnourishment.	(23)
DIABETES		
Diabetisource® AC	It's a mixture for tube feeding that contains pureed fruits and vegetables as a source of carbs for diabetes diet management	(28)
Boost Glucose Control®	It has thirty grams of protein. Because of this, it works well to avoid muscle weakness and maintain a stable level of fasting glucose	(29)
Glytrol®	Glytrol® is a medical food that contains readily absorbed carbohydrate blends to control blood sugar levels. It has additives of soluble prebiotic fiber to support a healthy digestive tract.	(30)
Betacell Glucofix	Glucofix is made to control the body's metabolism of glucose, maintain optimal blood sugar levels, and produce an antioxidant source.	(31)
CMD		
Vitabite	For patients who need to follow a protein-restricted diet because of an IEM, a chocolate with a high energy level and low protein content is recommended.	(24)
SMA LF®	This lactose-free medical formula is intended for infants who are intolerant to lactose. Up to 18 months old babies can use it.	(25)
PKU Start™	This PKU formula meal is free of phenylalanine and needs to be used under a doctor's supervision	(26)

Similac NeoSure	It offers complete nourishment to infants delivered before 37 weeks of pregnancy. Proteins, vitamins, and minerals have all boosted in this unique mix	(27)
Anxiety & Sleep disorder		
GABADone, and quality of sleep	It treats anxiety and sleep disorders, and the quality of sleep are both influenced by amino acids. Research has shown that the manufactured medicinal food extends and reduces sleep latency.	(17)
Pain syndromes		
Percura	It was shown that over the course of 21 days, patients with peripheral neuropathy saw an 82–89% decrease in pain and numbness.	(18)
Trepadone	It is a medication that has been specifically created to address the unique amino acid requirements required in the alleviation of chronic pain syndromes linked to joint diseases.	(18,19)

7. Conclusion

In particular, FSMPs and FS are utilized to manage and prevent chronic illnesses in the senior population. Degenerative illnesses progress over time as a result of stress, that cells and tissues experience as they age. In elderly patients, particularly those over 80, medications are frequently useless. Medical foods present a possible substitute for traditional diets, as they are specially designed to address specific diseases or conditions. Nonetheless, society does not know enough about medical foods, which highlights the need for more study. Numerous chronic illnesses, such as neurological diseases, anxiety and sleep problems, pain syndromes, cancer, congenital metabolic disorders, and diabetes, can be treated using medical foods. To increase public knowledge and provide new nutritional guidelines for medical use, more thorough research is required. Legal protocols are also essential for processing, distribution, and production. It takes specialized training programs to develop knowledge in the medical food sector. For individuals with more serious chronic illnesses, medical foods may be added therapies that complement medication to enhance patient outcomes.

Acknowledgements

We would like to express our sincere gratitude to IJDRA Journal for publishing our work.

Financial Disclosure statement: The author received no specific funding for this work.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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