SNE Specialised Nutrition Europe











STRONG CASES FOR MEDICAL FOODS IN EUROPE

Case book

Foreword

Medical Foods should be part of the plan for a healthier EU

The European Union's policymakers are rightly making health a priority. As Europe's population ages and chronic diseases become more prevalent, our healthcare systems are facing growing pressure. While much attention has been given to pandemic preparedness, access to medicines, and medical devices, an essential element of patient care remains overlooked: **nutrition**.

Various European initiatives aim to promote healthy eating. Yet, there appears to be a significant lack of awareness and absence of policy measures at the EU level to advocate for nutritional solutions specifically designed for **patients**. Medical foods, or Food for Special Medical Purposes (FSMP), are uniquely designed to support individuals with specific diseases or medical conditions at all stages of life, offering essential benefits that cannot be met through a standard diet. They not only improve patient outcomes but can also contribute to the sustainability of healthcare systems by reducing treatment costs and hospital stays.

With this brochure, we invite you to explore **why medical foods matter** – for patients, for healthcare professionals, and for policymakers. Through the experiences of four individuals who rely on medical foods, we highlight their impact on people's lives. While their names and images have been changed for privacy, their stories are real.

We believe it is time for EU policymakers to recognise the value of medical foods and ensure they are fully integrated into healthcare policies. **Nutrition is not a lifestyle choice – it is a fundamental part of patient care**.

About Specialised Nutrition Europe (SNE)

At Specialised Nutrition Europe (SNE), we unite and represent the specialised nutrition industry across Europe to contribute to positive framework conditions for products for people with specific nutritional needs. These include infants and young children, people with medical conditions, disorders and diseases comprising inter alia coeliac disease, sports people and those managing their weight.

As part of our policy asks, we encourage the development of an EU nutrition and health agenda with all stakeholders to tackle today's societal challenges such as obesity, malnutrition or food allergies.

Please consult our website for more information:

https://www.specialisednutritioneurope.eu/

Our presence in Europe

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What Are Medical Foods?

Foods for Special Medical Purposes (FSMP), often referred to as medical foods, support the dietary management of disease in patients from infancy to old age. They are specifically designed for individuals whose disease, disorder or medical condition temporarily or permanently affects their ability to achieve adequate nutritional intake through regular foods alone.

FSMP are developed on the basis of robust scientific and clinical evidence, in close collaboration with scientists and often with healthcare professionals (HCP), and are supported by national, international or professional guidelines where appropriate. Their composition is tailored to respond to disease-related nutritional needs arising from a wide range of medical conditions, including disease-related malnutrition, cancer, gastrointestinal and neurological conditions, renal disease, metabolic and rare disorders.

A defining characteristic of FSMP is that they are used on the recommendation of, and under the supervision of, a healthcare professional. The use under medical supervision ensures that the appropriate nutritional intervention is selected according to the patient's medical condition, stage of treatment and nutritional status, and that its use is monitored and adapted when necessary.

FSMP are consumed across all healthcare settings, including hospitals, outpatient clinics, long-term care facilities and patients' homes, enabling continuity of nutritional care throughout the healthcare pathway. Importantly, FSMP have their own specific regulatory framework within EU food legislation, clearly distinguishing them from food supplements, fortified foods, medical devices or medicinal products.



Behind the Policy, a Life

Four cases where FSMP help

Behind every policy discussion are real people whose daily lives, health, and fundamental dignity depend on appropriate timely access to nutritional care. The following four patient stories show how medical foods are not merely dietary options – they are indispensable to preserving daily functioning, and long-term quality of life across different medical conditions.

1 When Early Diagnosis is Important

How the right and timely diagnosis restored Sophie's growth



Cow's Milk Protein Allergy

Name: Sophie

Age: 3 years old

Condition: Cow's milk protein allergy (CMA)

Nutritional Need: Cow's milk protein-free medical formula

Nutritional Therapy: Extensively hydrolysed formula (FSMP under healthcare professional supervision)

Sophie thrived in her first months. When cow's milk protein slowly entered her diet, she began to vomit repeatedly and refused to feed. Over one weekend her symptoms worsened and as she seemed severely dehydrated, her parents took her to the hospital. Clinical evaluation and allergy testing gave the answer: cow's milk protein allergy. Her immune system was reacting to a protein that a majority of infants tolerate without difficulty.

Cow's milk protein allergy results from an immune reaction to cow's milk protein present in regular formula that is based on cow's milk protein. What all cases have in common is the need to completely eliminate cow's milk protein from the infant's diet while ensuring that the replacement feeding provides all the nutrients required for normal growth and development.

For Sophie, that meant use of a specialised formula with extensively hydrolysed protein, started under her paediatrician's supervision with dietary follow-up by her dietitian. Her symptoms settled and she resumed normal growth. As she grew, follow-up testing showed she was developing tolerance, and dairy was gradually reintroduced under medical guidance — the course most children with CMA follow.

Sophie is three now, healthy and energetic. Her story demonstrates the importance of early diagnosis and the prompt introduction of appropriate nutritional management.

The Role of FSMP

Cow's milk allergy is **one of the most common and disruptive dietary challenges in infants**. Because babies depend entirely on milk for survival during their first months, removing it without a therapeutically equivalent alternative rapidly triggers severe nutritional deficiencies and immediate growth failure.

Specialised formulas or FSMP specially designed for infants, such as extensively hydrolysed or amino-acid-based formulas[1], are designed specifically for infants who cannot tolerate standard formulas. These products ensure that children receive all essential nutrients while avoiding the allergenic proteins responsible for symptoms.

Early nutritional intervention does more than address immediate symptoms. It provides the nutritional support infants need to grow, develop and reach their full potential.

Breast milk is the preferred source of nutrition in early life. Where breastfeeding is not possible or is not chosen, infant formula may be used as an alternative. In infants with CMA, nutritional management requires the use of an appropriate specialised formula under the supervision of a healthcare professional, to support normal growth and development while excluding cow's milk protein.



Access, Clinical Guidance, and System Support

Sophie's case illustrates the value of timely diagnosis and early nutritional intervention. Healthcare professionals play a central role in identifying CMA, prescribing appropriate nutritional management and monitoring progress.

Access to suitable specialised formulas (infant FSMP) is also important, as cost can present a barrier for some families. **Reimbursement and coverage policies can help ensure that appropriate nutritional management is available to those who need it and that treatment decisions are guided primarily by clinical considerations.**



[1] *Hydrolysed formulas contain proteins broken down into smaller peptides to reduce allergenicity, while amino-acid-based formulas contain free amino acids and are used for infants with severe or multiple food protein allergies.*

2 When Swallowing Becomes Challenging

Evelyn's Silent Battle with Dysphagia

Dysphagia

Name: Evelyn

Age: 58

Condition: Stroke-related dysphagia

Nutritional diagnosis: Malnutrition due to swallowing difficulties

Nutritional therapy: Tube feeding followed by texture-modified FSMP (thickened foods and drinks)



At 58, Evelyn was a dynamic, independent woman deeply invested in her career and family. The stroke she suffered was a sudden shock, but her initial physical recovery exceeded expectations. She could walk, she could speak, she could smile. However, a much darker crisis began unfolding silently in the weeks that followed: Evelyn was losing the ability to swallow. A simple, automatic act like drinking a glass of water or swallowing a piece of bread became an agonising ordeal of choking, coughing fits, and panic. Over the following two months, she lost 10 kilograms. Unbeknown to her, some food and liquids were entering her lungs without obvious symptoms, a condition known as silent aspiration, which eventually led to pneumonia and hospitalisation. Her strength declined, daily tasks became exhausting, and she increasingly depended on others for basic activities.

At the hospital, a multidisciplinary medical team intervened, diagnosing **severe dysphagia compounded by profound malnutrition**. To halt her physical decline, Evelyn was initially nourished via a nasogastric tube. While psychologically uncomfortable, this step was vital to provide her basic nutritional needs. Simultaneously, a speech and language therapist began essential swallowing rehabilitation exercises. As her condition improved, Evelyn gradually transitioned from tube feeding to **specialised thickened drinks and texture-modified foods**, specifically designed to make swallowing safer while still providing complete nutritional support.

With continued monitoring by healthcare professionals and appropriate nutritional therapy, she regained strength and confidence. A few weeks later, she was able to return home and live independently again.

The Role of FSMP

Swallowing disorders (dysphagia) are common after stroke and can significantly increase the risk of **malnutrition, dehydration**, and aspiration pneumonia if not properly managed. Dysphagia is also frequently observed in elderly populations and in chronically progressing neurological diseases such as multiple sclerosis or amyotrophic lateral sclerosis[2], where the risk and severity of swallowing difficulties tend to increase over time. Despite its serious impact, it is widely underdiagnosed, leaving patients vulnerable to preventable, fatal lung infections, and long-term hospitalisation.

Early nutritional screening and timely access to medical foods, such as tube feeding formulas, oral nutritional supplements, and thickened foods, are essential to prevent complications and support recovery. Equally important is **accessibility**.



Access, Clinical Guidance, and System Support

Evelyn's journey highlights the important role of nutritional management in supporting recovery from dysphagia. Adequate nutrition and hydration help maintain nutritional status, preserve muscle mass and support participation in rehabilitation programmes. Early dysphagia screening, appropriate dietary management and access to suitable nutritional products can help reduce the risk of complications, including aspiration pneumonia, and improve patient outcomes. Reimbursement and coverage policies can also help ensure that patients have access to recommended nutritional interventions, supporting them in maintaining independence and quality of life.

[2] debilitating disease with varied aetiology characterised by rapidly progressive weakness, muscle atrophy and fasciculations, muscle spasticity, difficulty speaking (dysarthria), difficulty swallowing (dysphagia), and difficulty breathing (dyspnoea).

3 The Burden of Cancer-Associated Malnutrition

Thomas's Journey Through Cancer and Its Nutritional Challenges



Cancer and Malnutrition

Name: Thomas

Age: 34 at first diagnosis (now 37)

Condition: Mantle cell lymphoma

Nutritional diagnosis: Cancer-related malnutrition and weight loss

Nutritional therapy: Oral nutritional supplements (ONS) under medical supervision

At just 34 years old, Thomas received the life-changing diagnosis of mantle cell lymphoma, an aggressive blood cancer. His treatment involved intensive chemotherapy followed by a stem cell transplant.

The therapy was lifesaving, but it came at a cost. Thomas developed severe infections and struggled to eat or drink. Chemotherapy altered his sense of taste – foods he once enjoyed became metallic or unpleasant. His appetite disappeared. Despite knowing how important nutrition was for recovery, he simply could not eat enough. Within weeks, Thomas lost a significant amount of weight. His strength declined, fatigue worsened, and at one point, doctors had to reduce parts of his treatment because his body was too weakened by weight loss.

At that stage, his medical team introduced **oral nutritional supplements**, specifically designed to provide concentrated energy and protein in small volumes. These products helped him stabilise his weight and better tolerate treatment. The transplant was successful, and Thomas finally started to see a glimmer of hope on the horizon.

However, three years later, the shadow of cancer returned. This time, he qualified for an innovative CAR-T cell therapy[3] trial. Remembering his first experience, Thomas prioritised his nutritional status from the beginning. Working closely with his healthcare team, he incorporated medical foods early into his treatment plan.

Today, Thomas is once again cancer-free. He attributes part of his strength during treatment to maintaining his nutritional status alongside advanced medical care. Ultimately, after a long, arduous journey marked by profound uncertainty, he has finally reached a place of healing and renewed hope for the future.

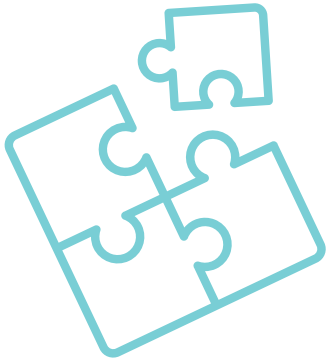


The Role of FSMP

Malnutrition is one of the most common and serious complications in cancer patients: it is a fatal disease within a disease. Global scientific data is stark: a comprehensive meta-analysis of over 31,000 oncology patients reveals that 41% suffer from malnutrition, with 20% classified as severe. Cancer-related malnutrition and cachexia (the systemic wasting caused by tumours) are estimated to be the direct cause of death for 20% to 30% of all cancer patients — harming them before the cancer cells can spread.

Cancer and its treatments often lead to symptoms that make eating difficult at a time when nutritional needs are higher. Patients may experience loss of appetite, changes in taste and smell, nausea, mucositis that makes swallowing painful, or even dysphagia. Combined with persistent fatigue, these effects can significantly reduce oral intake precisely when metabolic demands are increased, accelerating nutritional decline. Clinical guidelines from major scientific societies recommend early nutritional screening and intervention in cancer patients. When regular food intake is insufficient, oral nutritional supplements can provide the additional energy and protein required to help maintain nutritional status and support recovery.

3 CAR-T (Chimeric Antigen Receptor T-cell) therapy is an advanced immunotherapy in which a patient's own immune cells are genetically modified to recognise and attack cancer cells. It is used mainly for certain haematological cancers when conventional treatments are ineffective.





Access, Early Intervention, and System Support

Thomas's experience illustrates the importance of integrating nutritional care into routine oncology practice. Malnutrition is associated with poorer treatment tolerance, a greater risk of complications and increased healthcare utilisation. Early nutritional screening, assessment and intervention can help support patients throughout their treatment journey and may reduce the need for treatment modifications related to nutritional decline. Access to appropriate nutritional support, guided by trained healthcare professionals and supported by suitable reimbursement pathways, can help ensure that patients receive recommended care when they need it. Integrating nutrition into standard oncology pathways helps support both patient outcomes and the effective delivery of cancer care.



Thomas's story demonstrates that advanced oncology treatments and specialised medical nutrition are the two pillars of the same fight for survival.

4 When a Bowl of Pasta Needs a Second Thought

13-year-old Nina's Life with Maple Syrup Urine Disease

Name: Nina

Age: 13 years

Condition: Maple Syrup Urine Disease (MSUD)

Nutritional therapy: Lifelong specialised amino-acid-based FSMP and low-protein medical foods



Nina was born after a healthy pregnancy. Her parents initially experienced a content and healthy infant. However, on her fourteenth day of life, her health deteriorated significantly as she began refusing breast milk and became unusually drowsy. Concerned, her parents brought her to the emergency department, where her condition quickly worsened and she required intensive care. Doctors soon diagnosed Nina with **Maple Syrup Urine Disease (MSUD)**, a rare, inherited genetic metabolic disorder. Nina's body lacked the enzyme required to break down three essential amino acids (leucine, isoleucine, and valine). These elements were accumulating in her bloodstream, transforming into a lethal neurotoxin that was actively destroying her brain cells.

Luckily, treatment started immediately. Nina received a **specialised amino-acid-based medical formula** designed to provide all essential nutrients while excluding the amino acids her body cannot process. Within days, her condition stabilised, and she gradually recovered.

Today, Nina is a bright 13-year-old student. Her life remains a permanent, delicate balancing act. For Nina, an ordinary bowl of pasta, a piece of chicken, an egg, or a glass of milk is not an option. Her diet is carefully calculated, and much of her daily nutritional needs are met through specialised medical foods, including protein substitutes and specially produced low-protein staples such as bread, pasta, and rice. These specialised foods keep her nourished and provide the essential vitamins, minerals and other nutrients while having her protein intake highly restricted.

The Role of FSMP

Inborn errors of metabolism (IEM) are rare genetic conditions in which the body cannot properly process certain nutrients. These conditions demonstrate that nutrition can be much more than dietary support. For people living with MSUD, specialised nutritional management is a key therapeutic intervention. While no treatment can fully replace the underlying enzyme deficiency, carefully managed diets and specialised medical foods help maintain metabolic control and reduce the risk of serious complications.

Newborn screening and early dietary management are critical for children with MSUD and other inherited metabolic disorders. Without appropriate dietary treatment, patients are at increased risk of severe metabolic and neurological complications. Access to these specialised nutritional products helps support healthy growth, neurological development and long-term quality of life.



Access, Early Intervention, and System Support

For patients such as Nina, lifelong access to FSMP and other specialised nutritional products is essential for maintaining metabolic control. Delays in access or interruptions in supply may increase the risk of metabolic complications and place additional demands on healthcare services. Effective healthcare systems should support timely access to these products, minimise financial barriers where possible, and provide ongoing specialist dietary counselling across the patient's lifespan.

The Bottom Line

The stories of Sophie, Evelyn, Thomas, and Nina show that behind numbers and medical policies are **real people fighting for their lives, alongside the families and caregivers who fight with them every single day**.

Too often, medical nutrition is overlooked. It is frequently misunderstood as just a "dietary option" or a secondary support. These stories prove that this is a dangerous misconception. For a baby with severe allergies, a stroke survivor who cannot swallow, a cancer patient fighting exhaustion and malnutrition, or a child with a metabolic disorder, medical foods are **not an optional add-on**. They are not simply a source of nutrition; they are an essential part of their overall treatment plan.

For Nina, dietary management is part of everyday life. Access to specialised low-protein foods helps her follow the strict dietary requirements of MSUD while participating in the same activities as her peers. Whether at school, with friends or at social events, these products can help reduce the practical and emotional burden associated with managing a lifelong metabolic condition.

Across all these stories, one message is clear: appropriate nutritional care can play a critical role in supporting health outcomes. Whether providing a nutritionally complete alternative for an infant with cow's milk allergy, helping a patient with dysphagia maintain adequate nutrition, supporting a person through cancer treatment, or enabling lifelong management of a rare metabolic disorder, medical nutrition is often an essential component of care. Its contribution extends beyond meeting nutritional needs and can help support treatment, recovery and quality of life.

Effective healthcare requires more than diagnosis and treatment alone. For many patients, **specialised nutritional products are an essential component of care**, helping to support growth, recovery, treatment tolerance and long-term health. Ensuring timely and equitable access to appropriate medical nutrition should therefore be regarded as a core element of healthcare delivery, rather than an optional addition to it.

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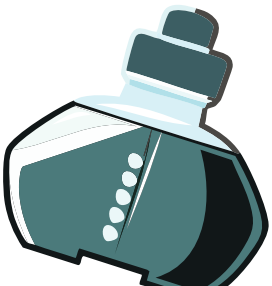
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General Question
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