Innovation & New Product Development in Medical Nutrition


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The phrase *'necessity is the mother of all invention'* has completely underpinned the development of medical nutrition products over the last 50+ years. With the increasing recognition of nutrition being a crucial and absolutely necessary part of patient care, the medical nutrition industry has led the way in innovating and producing patient-focused solutions to enhance nutritional care across a range of therapy areas. Dietitians and other healthcare professionals often only see the end result and not the complexity and process driven approach that is involved in the development of new medical nutrition products. This article explores the process and challenges that are involved in developing new medical nutrition products to enhance patient care.

What's the problem?

New product development often starts with trying to find a solution to an issue or a problem. This could be trying to develop a more palatable life-saving protein substitute for a complex condition, such as phenylketonuria (PKU), or a more convenient format of an oral nutritional supplement that is easier for patients to consume with the aim of improving compliance. Understanding the problem that needs to be solved is the very starting point of the new product development process. In the field of medical nutrition, this may also be informed by emerging research, for example, on the benefits of a new ingredient in a particular new therapy area or patient group.

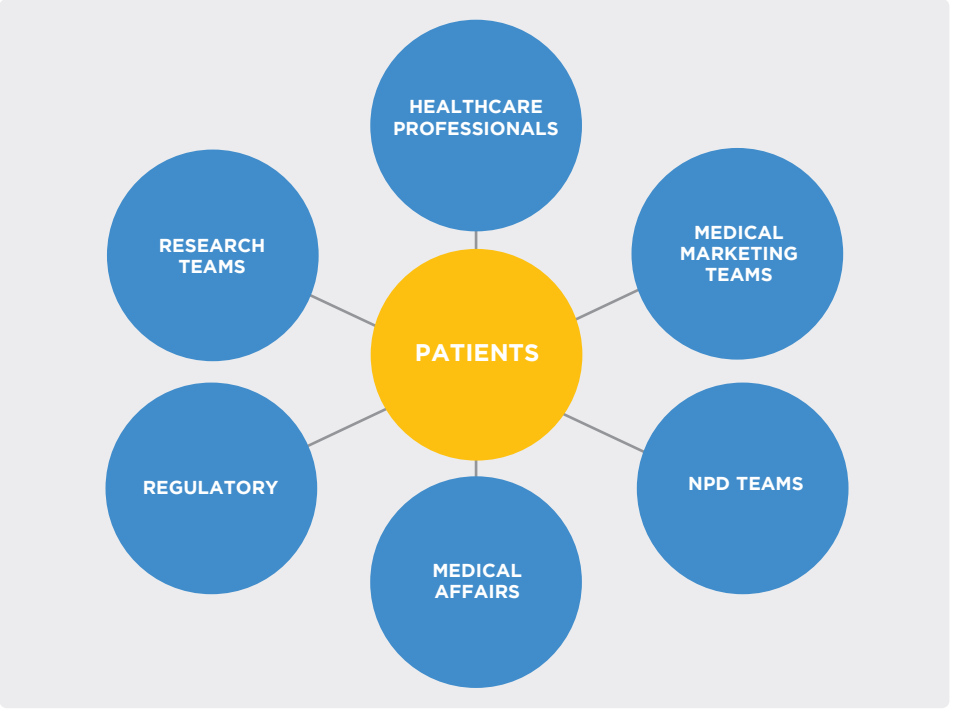
Horizon scanning is also important as trends in consumer food manufacture and changing consumer habits may have a knock-on effect to the needs of patients. For example, the rise in consumer vegan and plant-based diets has created increased interest in medical nutrition products suitable for vegans.

Once a concept has been formalised, many medical nutrition companies will engage with customers using a focus group approach, bringing together relevant healthcare professionals to give honest and open feedback on new concepts. These are often facilitated by an independent market researcher to moderate the response and reduce the risk of bias in the process. For some concepts, this may involve groups of international experts as new product development may be focused on patient needs in other countries, not just the UK. Patient organisations or patient support groups may also be consulted.

Multidisciplinary process driven approach

Comparable with achieving the best patient care for complex conditions, successful product development requires a multidisciplinary approach, bringing together the unique skills of a range of professionals (see **Figure 1**). For example, concept development often starts in the medical marketing team alongside input from medical affairs/research teams and regulatory teams. Engagement with new product development teams within the factory is also a key stage of early development.

Figure 1: Range of expertise required for successful new product development



New product development requires a process driven approach, with as many as 50 steps required to successfully bring a new product to market. Project management skills are essential as there are many hurdles to overcome with any new medical nutrition product, and input is required from different functions at various points. Timelines will vary depending on the product, but typically this would be around 3–10 years from concept to launch. Timelines are also dependent on other factors that are outside of a company's control, such as regulatory approval for re-imbursement.

Technological challenges

One of the many challenges of producing medical nutrition products is the desire to achieve maximum nutrition in a small volume. There is often a balance between the desired nutritional profile *versus* what is possible from a technological viewpoint versus what is acceptable to the patient. This is one of the reasons why dietitians and nutritionists need to work together with product technologists and marketing teams to achieve the best outcome, i.e. a product that delivers on nutrition but can also be successfully manufactured and is acceptable to the patient.

Other manufacturing professionals, such as process technologists and production managers, need to ensure that the factory has the right equipment, and process to make the product, alongside the capacity to undertake pilot and industrial trials to check shelf life and stability. For companies that use third-party suppliers, there is also an initial stage of auditing the manufacturing partner to ensure that they adhere to the highest internal standards of food manufacture and have the right manufacturing accreditations in place.

Sensory testing

Sensory testing is undertaken at several stages of the product development process. Many manufacturers will have in-house sensory testing panels that might initially be involved, depending on the product and target audience. However, as medical foods are consumed by patients with medical conditions, it is vital that sensory testing is conducted with the patient group for which the product is designed. This is important as it is well recognised that older people have different sensory perceptions than younger people, and hospitalised older people may have further alterations to their taste perceptions.[1, 2] If sensory testing is carried out in order to make a marketing claim (e.g. 'best tasting'), it is important that this is conducted with a big enough sample size to allow statistical analysis according to the Medical Nutrition Industry Code of Conduct.[3]

Packaging

The decision as to what packaging the product is put into is usually made early in the product development process. Packaging is important as all medical foods need to ensure that the nutritional, microbiological and organoleptic integrity of the product is maintained over its shelf life.

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Patients must be able to handle the packaging with ease, which is also a crucial component of the packaging decision. However, packaging capability is often fixed within a factory, so the ability to swap to a new packaging size or format is impossible unless long-term significant investment is put in place at factory level. Packaging innovation has historically been led by industry in response to patient and healthcare professional feedback and should continue to evolve in this way.

Product labelling

Product labels need to be prepared and this usually involves a third-party design agency. Labels have to be approved internally by suitably qualified professionals, usually the regulatory team, to ensure that they comply with labelling legislation. Despite medical foods having their own labelling requirements, they are also subject to general food labelling regulations that require certain aspects to be included on labels, e.g. allergen labelling.[4] Before launching a new medical food, companies have to submit labels to the Department of Health and Social Care to notify them that the product is being placed on the market. Although this is generally a formality, it is one of the requirements of the Foods for Special Medical Purposes (FSMP) legislation.[5]

Clinical research studies

One of the final stages of the product development process is to conduct clinical studies, and these are usually conducted within the UK. The aim of these studies is to explore the efficacy, tolerance, palatability and compliance of the medical nutritional product, and the study design will vary depending on the product and its clinical use to ensure appropriate and robust data are captured. Typically, the products are trialled in the community to mimic the usage of the product on prescription.

Key contributors to these studies are the investigators, who are primarily dietitians as they are responsible for reviewing a patient's nutritional requirements and recommending medical nutrition prescriptions where appropriate. The investigators work closely with patients, their local research and development department and study monitors to ensure good clinical practice is followed. As many who are involved in research know, the process can be challenging but rewarding; investigators play a key part in driving the success of the trial, including trial set-up, patient recruitment and data management.

The results from these clinical studies are used to support product use in clinical practice. Results are shared with dietitians to demonstrate the product's efficacy and use, and occasionally the results are presented at conferences or published in scientific peer reviewed journals. The results also support the listing of the product in the Drug Tariff, allowing it to be prescribed in the community. This requires approval from the Advisory Committee on Borderline Substances (ACBS), who are responsible for advising on the prescribing of nutritional and dermatological products for use in NHS primary care. The ACBS meet three times a year, so product applications need to be made according to specified dates. The approval process can be lengthy, with applications more recently being asked to be re-submitted multiple times prior to approval.

Conclusion

Product development within the medical nutrition industry is complex and time consuming. Companies plan many years in advance before launching a new product, considering multiple factors such as emerging research, ingredient innovation, technological and manufacturing capabilities and packaging innovation. New product development is always underpinned by patient need, often across multiple countries rather than just the UK. Achieving the best innovations to support patient care requires a medical nutrition industry that has the flexibility and freedom to innovate.

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