# INNOVATION AND NEW PRODUCT DEVELOPMENT IN MEDICAL FOODS

Catherine Hodgson
Public Affairs Manager, British Specialist Nutrition Association (BSNA)

Martha Jackson
ANutr
Scientific and Regulatory Executive
British Specialist Nutrition Association Ltd (BSNA Ltd)

**In this article we explore the process and challenges involved in developing new medical foods, otherwise known as food for special medical purposes (FSMPs), to ensure patients have access to the best innovations to support effective nutritional care.**

Over the last 50+ years, the medical food industry has led the way in innovating and producing patient-focused solutions to enhance nutritional care across various therapy areas. Product development is complex and time-consuming and for healthcare professionals (HCPs), the process-driven approach is not often explained in detail. Innovations of medical foods, otherwise known as Foods for Special Medical Purposes (FSMPs), get assessed and approved for reimbursement in the community by the Advisory Committee on Borderline Substances (ACBS), which is part of the Department of Health and Social Care (DHSC).

New product development often starts with trying to find a solution to an issue or a problem – whether this is trying to develop a more palatable life-saving protein substitute for a complex condition such as phenylketonuria (PKU) or an easier-to-consume format of an oral nutritional supplement (ONS) to improve compliance.

Understanding the problem is the starting point and this may be informed by emerging research. Horizon scanning trends in consumer food manufacture and changing consumer habits that may impact the preferences of patients are also important; for example, the rise in vegan and plant-based diets. Once a concept has been formalised, medical food companies will engage with customers and relevant HCPs so they can give their feedback.

## MULTIDISCIPLINARY PROCESS-DRIVEN APPROACH

Successful concept and product development requires a multidisciplinary approach, bringing together the unique skills of a range of professionals. Project management skills are essential due to the complexity and number of steps involved.

Concept development starts in the medical marketing team, alongside input from medical affairs/research and regulatory teams. Engagement with new product development teams within the factory is also key at the early development stage to ensure manufacturing viability.

Timelines will vary depending on the product development process and on other factors outside of a company's control, such as regulatory notification to the Nutrition Legislation Team, which is required prior to ACBS approval for reimbursement, a process that has currently been taking up to six to 12 months. Therefore, a typical timeline could be around three to 10 years from concept to launch.

## TECHNOLOGICAL CHALLENGES

In seeking to achieve maximum nutrition in a small volume, manufacturers have to balance the desired nutritional profile, what is possible from a technological viewpoint and what is acceptable to the patient. Dietitians and nutritionists working with product technologists and marketing teams are key to this process to ensure a product delivers on nutrition and can also be successfully manufactured, whilst also being acceptable to the patient.

Teams, such as process technologists and production managers, also ensure the factory has the right equipment and process to make the product and there is capacity to undertake pilot and production trials to check shelf life and stability. For companies that use third-party suppliers, there is also an initial stage of auditing the

REFERENCES

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manufacturing partner to ensure they adhere to the highest internal standards of food manufacturing and have the right manufacturing accreditations in place.

## SENSORY TESTING

Sensory testing is undertaken at several stages of the product development process. While some companies may use in-house sensory testing panels for initial testing, companies conduct sensory testing with the relevant patient group for which the product is designed to ensure it meets their needs. For example, older people may have different sensory perceptions than younger people and hospitalised older people may have further alterations to their taste perceptions.[1,2] Companies carefully create and select flavours for products which will be best suited to the patient group they are intended for. If sensory testing is carried out to support a labelling statement (eg, best tasting), it is important that this is conducted with a large enough sample size appropriate for the medical condition, to allow statistical analysis according to the Medical Nutrition and Parenteral Nutrition Industry Code of Practice.[3]

## PACKAGING

Packaging is important since the nutritional, microbiological and organoleptic integrity of the product must be maintained over the shelf life of the medical food. In addition, patients must be able to handle the packaging with ease, particularly as some patients who use these products may have poor dexterity.

The decision as to what packaging is utilised is usually made early in the product development process. However, packaging capability is often fixed within a factory, so the ability to swap to a new packaging size or format is very difficult unless long-term significant investment is put in place at factory level.

## PRODUCT LABELLING

Labels are approved internally by suitably qualified professionals, usually the regulatory team, to ensure they comply with labelling legislation.[4] The products are also subject to general food labelling regulations that require certain aspects to be included on labels, eg, allergen labelling.[5] Under the regulations for medical foods, companies must then submit labels to DHSC, to notify them that the product is being placed on the market.

## CLINICAL RESEARCH STUDIES

Clinical research studies may be initiated at the final stages of new product development, through which the efficacy, tolerance, palatability and compliance to the medical food are explored. The study design will vary depending on the product and its clinical use to ensure appropriate and robust data are captured. Most studies are conducted in the UK and products will typically be trialled in the community to mimic the usage of the product to be made available on prescription.

The investigators running the clinical trial will primarily be dietitians, as they are responsible for reviewing a patient's nutritional requirements and are likely to be the HCP recommending medical food prescriptions where appropriate. The investigators will be involved in trial set-up, patient recruitment and data management, working closely with patients, their local research and development (R&D) department and study monitors to ensure good clinical practice is followed.

The results from clinical studies are used to support product use in clinical practice and are shared with dietitians to demonstrate the product's efficacy and use. Results are also required to support the listing of a product in part XV of the Drug Tariff, allowing it to be prescribed in the community in the UK. Medical food companies submit listing applications to the ACBS, which recommends the nutritional and dermatological products that should be made available on prescription in NHS primary care.

## CONCLUSION

Companies plan many years in advance before launching a new product, taking into account multiple factors such as emerging research, ingredient innovation, technological and manufacturing capabilities and packaging innovation, as well as patient and healthcare professional needs. New product development is always underpinned by patient needs, often across multiple countries including the UK. Achieving the best products to support patient care requires a medical food industry that has the flexibility and freedom to innovate. It is through innovation that we can truly unlock the power of nutrition in patient care.