

Medical Foods: an alternative route to market

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Government 'failing' on obesity crisis Which? has warned

Ministers are failing to act on the national obesity crisis and industry is not taking enough action to label calorie-content on menus, it has been warned.



Government statistics show that more than 60 per cent of adults in England and a third of 10 and 11-year-olds are obese Photo: ALAMY

Growing awareness

Advances in scientific understanding of the link between diet and health are translated into consumer behaviour by:

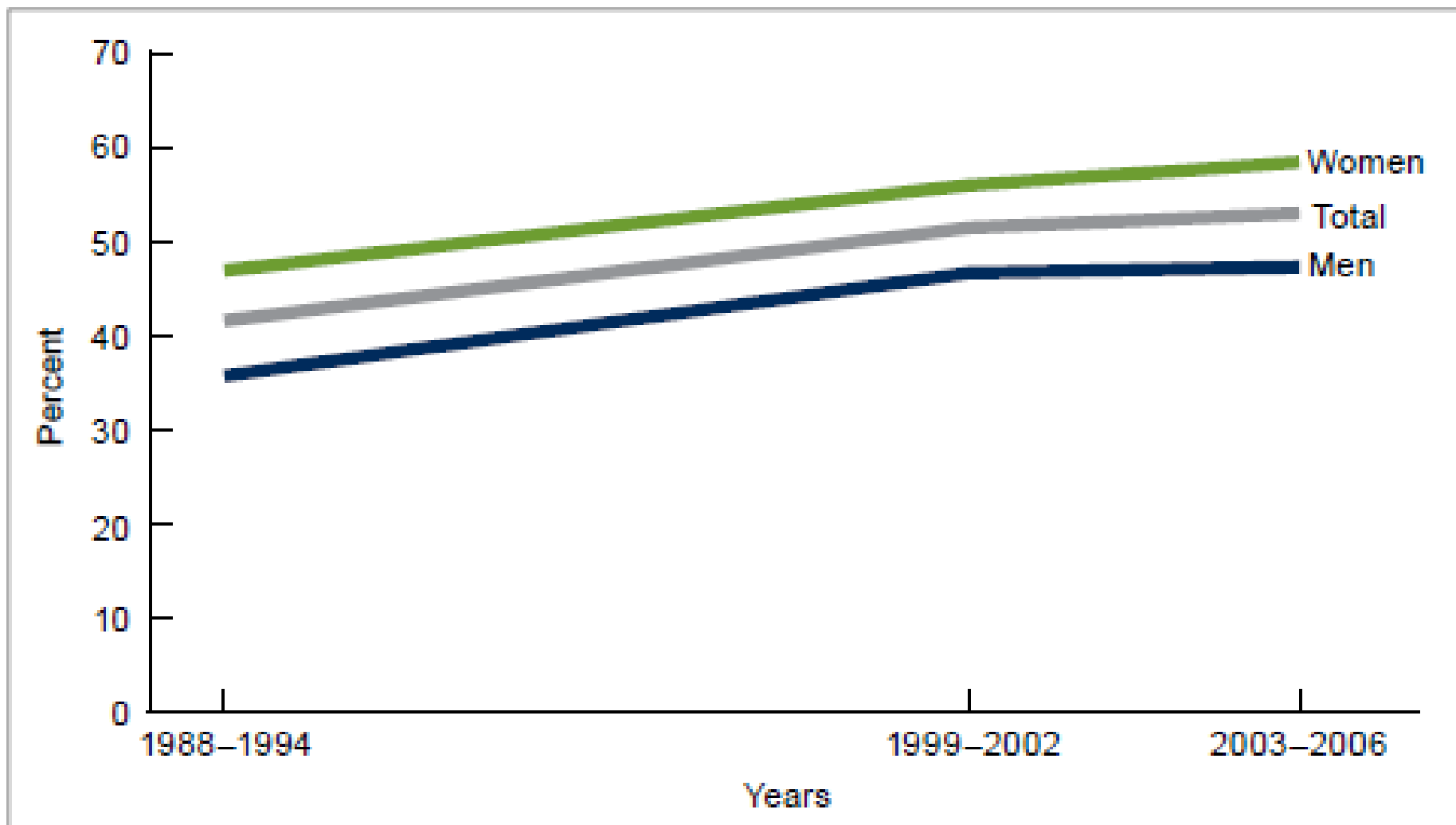
- Government education programs
- Nutritional labels on foods
- Product health claims
- Popular media, word of mouth
- Advice from physicians



Specialists physicians' recommendations for use of dietary supplements

	Cardiologists	Dermatologists	Orthopedists
Overall % who recommend to patients (n=300 of each specialty)	72%	66%	91%
Primary reasons given:			
Overall health & wellness	30%	30%	25%
Heart health	55%	12%	10%
Joint health	19%	-	73%
Bone health	22%	25%	75%
Lower (or maintain) cholesterol	94%	-	13%
Immune health/colds/flu	-	12%	7%
Skin, hair, nail health	-	81%	-
Musculoskeletal pain	-	-	53%

Trends in the percentage of persons using dietary supplements, by gender for adults aged 20 and over: United States, 1988–2006



NOTES: Significant linear trend from 1988–1994 through 2003–2006. Statistically significant difference for men compared with women for all time periods, $p < 0.05$ for comparison between genders within survey periods. Age adjusted by direct method to the year 2000 projected U.S. population.

SOURCE: CDC/NCHS, National Health and Nutrition Examination Surveys.

Some commonly used terms

- “*Nutraceuticals*”: non-specific term for food-derived products with health benefits
- *Functional foods*: foods enriched with ingredients deemed beneficial to health
- *Dietary/food supplements*: oral supplements of specific nutrients for healthy people
- *Medical foods*: preparations based on dietary ingredients for managing *medical conditions*

Omega-3 fatty acids – identity crisis?

- Food
- Food supplement
- Pharmacy medicine
- Prescription drug



M&S BUYS INTO CANCER-FIGHTING BROCCOLI

A UK-bred variety of broccoli believed to help ward off cancer and heart disease went on sale at Marks & Spencer stores today. Other superstores are expected to stock the product from 2012.

It has been bred by crop scientists at the Institute of Food Research and the John Innes Centre in Norwich.

The commercial success stems from groundbreaking work by one of the scientists at the in 1983, who discovered an Italian wild broccoli variety with higher levels of glucoraphanin.

Glucoraphanin is a beneficial chemical found naturally in broccoli and is thought to help explain the link between eating broccoli and lower rates of heart disease and some forms of cancer. Glucoraphanin also leads to a boost in the body's antioxidant enzyme levels.

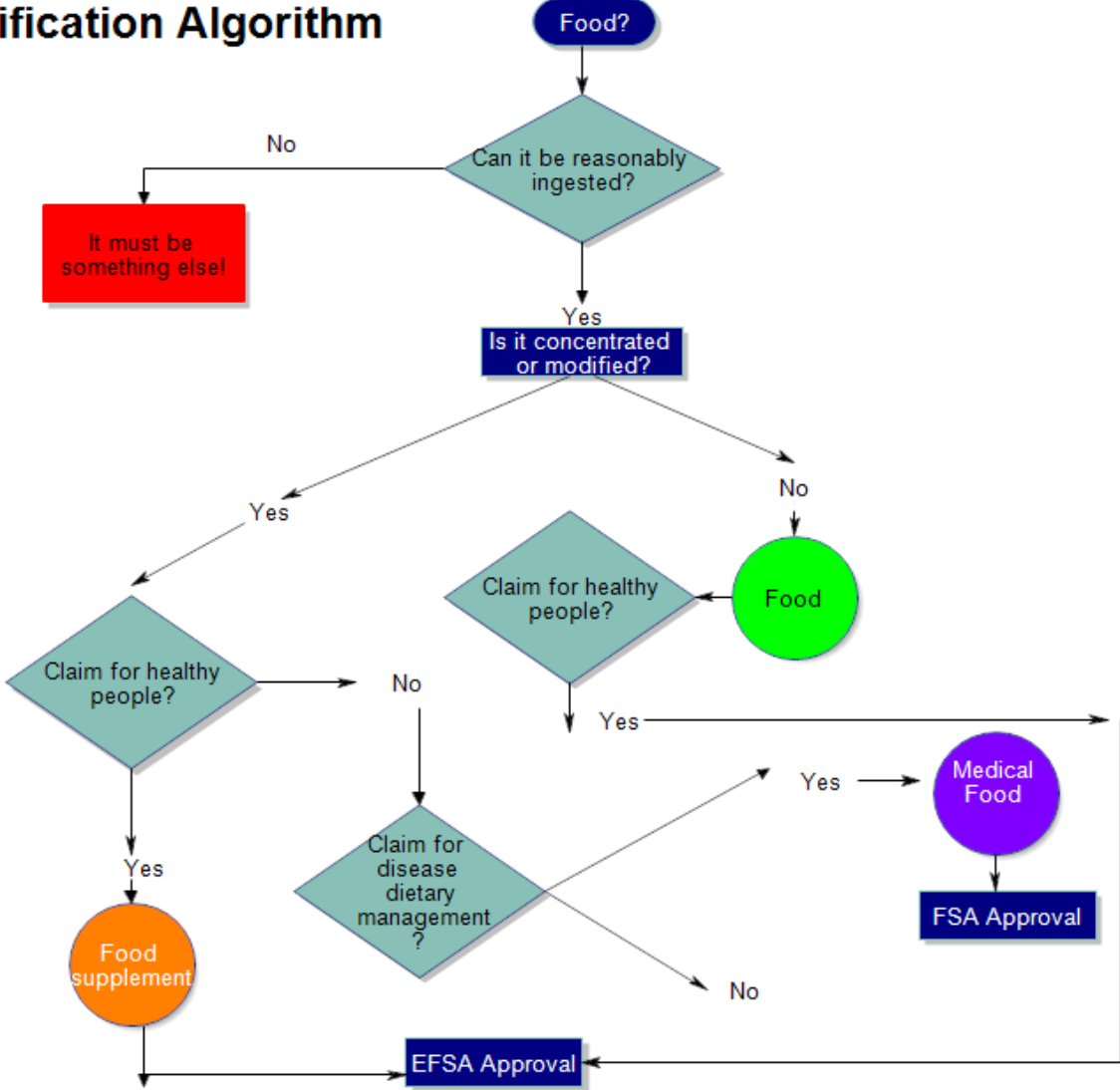


Approval of Health claims

European legislation states that health claims on foods and dietary supplements must be:

- *based on generally accepted scientific evidence*
- *well understood by average consumer*
- *based on a quantity and pattern of consumption that could reasonably be achieved as part of a balanced diet*

Classification Algorithm



EFSA's approach to health claims

- FruitFlow (tomato extract) was first to achieve a claim based on new scientific evidence
- Health claim allowed by European Food Safety Authority: *“Helps maintain normal platelet aggregation, which contributes to healthy blood flow”*



Would this mean anything to the average consumer?

Medical foods for medical conditions

- Medical Food claims are directed to **physicians**
- Medical Foods offer a dietary approach for a medical condition alongside drug therapy
- Distinctive nutritional needs occur with some chronic diseases, e.g. due to due to metabolic imbalances, malabsorption, impact of drug therapy, increased nutritional turnover
- Known concept (e.g. diabetes, coeliac disease)

Definition: Medical Foods

- Specially formulated and processed for oral (or tube) administration
- Intended for specific dietary management of a disease or condition which has distinct nutritional requirements
- Intended to be used under supervision of a physician, with ongoing care
- Ingredients 'Generally Recognised As Safe' (USA)

Limbrel® 500 (available in USA)

- Prescription product developed and formulated specifically to safely meet the distinctive nutritional requirements of patients with osteoarthritis through dual inhibition (COX + LOX) of arachidonic acid metabolism and anti-oxidant action rather than COX-2 selective inhibition.
- Contains flavocoxid, a proprietary blend of natural ingredients from phytochemical food source materials.



* Also in 250-50 mg BID.

Axona[®] (available in USA)

- Axona is intended for the clinical dietary management of the metabolic processes associated with mild to moderate Alzheimer's disease.
- Axona addresses the decline in glucose metabolism—a well-characterized feature of Alzheimer's disease
- Taking Axona produces ketone bodies, which the brain can use as an energy source
- Patients with mild to moderate Alzheimer's disease taking Axona demonstrated improved cognitive function
- Contains caprylic triglyceride



Suplena with Carb Steady (USA)

Suplena with Carb Steady is low-protein, therapeutic nutrition designed specifically for patients with reduced kidney function who are not receiving dialysis.

Suplena can help patients with reduced kidney function maintain their nutritional status, while adhering to their diets. Suplena is a medical food. Suplena should be used only under the advice and supervision of a doctor or medical professional.



Betaglucare[®] (available in EU)

- Betaglucare is a natural food from oats that lowers cholesterol and blood sugar.
- Betaglucare is approved as food for special medical purposes - Cholesterol / Diabetes; it can thus be included as part of the treatment of these diseases. Betaglucare lowers the GI by slowing absorption of carbohydrates.
- For the dietary management of diabetes mellitus type 1, type 2, and elevated cholesterol levels, use Betaglucare in consultation with your doctor or dietitian.
- Contains betaglucan



Cubitan (available in EU)

- Cubitan is a Food for Special Medical Purposes for use under medical supervision. Cubitan is a high protein, high energy, milkshake style nutritional supplement, designed for the dietary management of patients with chronic wounds.



Medical Food vs Drug Development

- Safety profile of key ingredients is already established so no requirement for lengthy toxicology studies
- Clinical studies must be robust as efficacy will be judged by 'drug' standards by clinicians
- No reimbursement procedure to delay launch
 - Faster and less costly route to market

InterPharm Investments Ltd

A *'search and development'* company

Our main search criteria:

- Evidence for potential medical benefits of a dietary ingredient (*e.g. animal studies*)
- Potential use in a specialist medical field (*e.g. gastroenterology, renal or cardiovascular medicine*)
- Strong IP and/or exclusivity over raw material
- Clear competitive advantages

InterPharm's approach

1. Assessment of the most suitable regulatory and development pathway
2. Review of IP and commercial issues
3. Licensing agreement (ideally worldwide)
4. Financing for formulation and clinical development (with partners)

Contact us: eevans@interpharminvestments.com