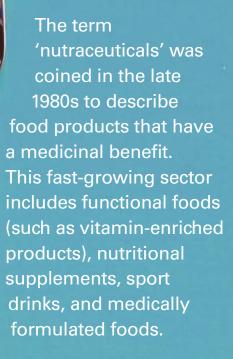


Nutraceuticals: The future of intelligent food

Where food and pharmaceuticals converge

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Where food and pharmaceuticals converge



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Background

Nutraceuticals is expected to play a central role in impact can be lessened by making healthier choices earlier in life. This leads to a sharper focus on measures, such as a health-promoting diet, to prevent people from not just new 'superfoods', to take one example, but also ways to persuade people to make better choices about their diet. The emphasis of the research may, therefore, be on computer applications, for example, that remind and promote exercise. These pill-replacing 'apps' could invigorate demand for new nutraceutical products designed to promote wellness.

Competitive landscape

This convergence of medicine, food and technology is likely to create a battleground in which food and pharma companies compete for dominance of the sector. The global market for functional foods certainly presents a big opportunity: sales are predicted to reach US\$250 billion by 2018¹, roughly five times larger than in 1999² This is substantial when compared with the \$900 billion \$5 trillion worldwide food industry⁴. Food companies have but their research expertise does not go as deep as that of the pharmaceuticals industry. Successful companies

Achieving success

Technology is going to play a crucial role in success. Companies who thrive are likely to be those that place bold longer in nutraceuticals than in food, and this should play to the strengths of pharma which is accustomed long lead Future 'superfoods' could tackle the underlying causes of conditions such as diabetes, obesity and cardiovascular disease, by linking diet to health. Competitive advantage will be gained by those companies with a superior product strategy, juggling ingredients, technology and labelling to

The potential market for nutraceuticals may be large, but a of national tastes. As the industry expands, the main players have to assure a steady supply of such ingredients vertically integrated to ensure stability.

The nutraceuticals industry is likely to see food and pharma at a premium. Big pharma and big food companies are not known for being nimbly entrepreneurial, so they will have to do a number of things that go against their corporate

Sector Report, Nutraceuticals Industry, Bourne Partners, April 2013 The Economist, September 9th, 1999, quoting Nutrition Business Journal http://www.economist.com/node/238647 http://www.abpi.org.uk/industry-info/knowledge-hub/global-industry/Pages/industry-market-.aspx Pegasus Agritech, Global food market http://pegasusagritech.com/hydroponics/global-food-market

Key nutraceutical product hot spots

Background: The WHO predicts that by 2020 over 65 million people will have dementia and that the prevalence of other neurodegenerative brain diseases, like Alzheimer's, is also increasing¹. The pressure to produce successful treatments is rising but has proved unsuccessful so far. Scientists are increasingly looking to food products to help slow disease progression and treat symptoms.

BRAIN HEALTH AND AGING

Pipeline: There are a range of products in the pipeline that attempt to improve cognitive function. Enhancing brain glucose metabolism to delay cognitive decline has been the target of some products, like Accera. There is also an increasing number of products which claim to enhance normal brain function, such as Neurozan. As adults become more aware of cognitive disease there will be a greater market for preventative treatments. With large investments happening in this area, there will be innovative products hitting the market within five years.

GASTROINTESTINAL HEALTH

Background: Gut health issues, from indigestion through to more serious conditions like celiac disease motivate consumers to look to over-the-counter symptom relief. It is estimated that over 100 million people globally are effected by 'gut health' problems and the prevalence is rising². Household products (like Yakult and Actimel, see page 14) help to provide some symptom relief. They have a positive effect on the millions of organisms that live in the human intestine (known as gut flora)³. Many consumers purchase some form of 'probiotic' product and the market is growing⁴.

Pipeline: There is continued investment into 'free from' products. This is driven by the increasing number of people claiming to be intolerant to certain ingredients, for example gluten and lactose, although few people have a diagnosed intolerance⁵. One example is Alpo's successful almond milk product offering an alternative for people with lactose intolerance, and claiming to have many other health benefits over cow's milk.

http://www.who.int/medicines/areas/priority_medicines/BP6_11Alzheimer.pdf

http://www.niddk.nih.gov/health-information/health-topics/digestive-diseases/Pages/default.aspx http://www.ncbi.nlm.nih.gov/pubmed/11590374 http://www.nutraingredients.com/Markets-and-Trends/Global-probiotics-market-to-grow-6.8-annually-until-2018

ccording to a recent survey 1 in 3 people claim to be 'intolerant of gluten

http://ajcn.nutrition.org/content/8/4/445.full.pdf

http://www.nutraceuticalsworld.com/issues/2013-03/view_features/gut-instincts-the-right-moves-for-protecting-digestive-health/#sthash.ynH0QZIG.dpuf

THE DOCTOR OF THE FUTURE WILL GIVE NO MEDICATION, BUT WILL INTEREST HIS PATIENTS IN THE CARE OF THE HUMAN FRAME, DIET AND IN THE CAUSE AND PREVENTION OF DISEASE. THOMAS EDISON

CARDIO & HEART HEALTH

Background: The impact of cardiovascular disease (CVD) is significant. It is the number one cause of death globally⁶. The risk of contracting CVD is associated with lifestyle choices including a poor diet. There are three main opportunities for nutraceuticals in heart health. The first is to reduce cholesterol, the second is to reduce the circulation of freeradicals (which contribute to plaque formation in arteries), and the third is through Fibrinolytic activity (plaque break down). Any food and drink that can demonstrate progress in these areas will have wide reaching impacts on the disease. **Pipeline:** There is already a suite of products that focus on cholesterol reduction, with most evidence supporting the role of Vitamin E and omega-3⁷. CardioMax is an omega-3 based nutraceutical produced by SevenSeas which claims to support a healthy heart. Preliminary research is being conducted to endorse products like Naticor, which use a combination of 'natural enzymes' to help promote fibrinolysis. Products which can demonstrate even a small health benefit in this area will prove to be successful.

ENDOCRINE HEALTH & DIABETES

Background: The WHO estimate that 347 million people worldwide have diabetes⁸. Sustained exposure to high blood glucose is linked to the consumption of high fat and high sugar content foods. Foods which release sugars slowly enable better glucose control which can reduce the impact of diabetes for sufferers, and can also help to prevent the onset of type 2 diabetes.

Pipeline: Recent success stories include European Food Standards Authority (EFSA) approved Benecarb; a low glycaemic index sugar substitute for diabetics. There are also a number of studies looking at food products that re-sensitize the body to insulin⁹. One product developing traction is a soluble fibre gum that has registered approval to claim it can increase insulin sensitivity following successful trial results.

The shift in healthcare from treatment to prevention is encouraging clinicians and patients to think differently about health and disease, and creating momentum for nutraceuticals, with opportunities for pharma and food companies to get involved in the disease/care pathway.

Professor Ajit Lalvani, Chair of Infectious Diseases, Imperial College, London and Non-Executive Director, Vitabiotics

Food versus pharmaceuticals

Food companies have a greater understanding than pharmaceuticals of nutrition and food formulation, plus decades of consumer research and relationships with mass-market distributors. Food companies who are doing well in nutraceuticals include those that have created separate health divisions, acquired successful brands, and launched global health improvement plans.

However, despite a commitment to innovation, food businesses lack some of the in-depth scientific resources that are needed to come up with major breakthroughs. Innovation in food tends to involve modest improvements such as reduced sugar, salt or fat levels, or novel-tasting products. As a result, food companies may struggle to achieve the kind of game-changing breakthroughs necessary to open up new nutraceutical markets. Furthermore, shareholders could be impatient over the longer development times associated with nutraceutical products.

Pharmaceuticals companies face a different set of difficulties. They have strong research departments, stakeholder relationships and regulatory structures that enable them to generate new compounds, plus wider ties to the scientific community. Yet, despite their large sales and marketing resources, most of their efforts are aimed at medical professionals and pharmacists rather than consumers. Only a small number of pharmaceutical companies have a consumer arm. An organizational culture devoted to blockbuster drugs and long research cycles may struggle to adapt to the faster pace of the nutraceuticals market. Among the pharmaceuticals companies with a strong presence in nutraceuticals, Abbott owns some of the leading nutritional product brands. Pfizer sells a range of dietary supplements. Johnson & Johnson makes products to lower cholesterol and dietary supplements for people who are lactose intolerant. Some pharmaceuticals companies have attempted wider public awareness campaigns for nutraceuticals, but few, if any, have the competence to influence behavioral change on a wide scale. There is also the question of how to accommodate consumer-oriented brands within existing portfolios, with such products typically delivering smaller margins than traditional drugs.

By complementing each other's strengths (and weaknesses), a merger of the nutraceuticals portfolios of a big food company and a big pharmaceuticals company might make sense, but there hasn't been a significant one yet. Instead, there has been a blurring of the line demarcating the two industries and an active market for corporate transactions involving relatively small acquisitions and sell-offs. These maneuvers are preliminary skirmishes; the battle for dominance in the nutraceuticals market seems a long way off. But the war against chronic and lifestyle related diseases is already in full swing. Functional 'superfoods' probably have an important role to play in the struggle, and it's only a matter of time before the fight spills over into corporate takeover wars.

At some point, a nutraceuticals powerhouse will emerge, but what will it take to build one? Whether it grows organically or by acquisitions or a combination of the two, certain key attributes will be required.

Nutraceuticals cover a wide range of products, from sports drinks available on supermarket shelves to prescription drugs for patients with serious medical conditions

Nutraceuticals represent an exciting new opportunity for food and pharmaceutical companies to diversify

CHALLENGES



Declining return on R&D investment 'Patent cliff' Pressures on health budgets

Regulatory oversight

Slow-growing

Retailer-owned brands

Retailer power

Internet marketing

RELEVANCE OF NUTRACEUTICALS

New sector with lower R&D costs New revenue source Most purchases are by consumers Less onerous regulatory requirements Fast growing Source of differentiation & higher margins Innovative products increase bargaining power

Accepted channel for new products

Technological boldness

Much of the technological progress in the field of nutraceuticals will require patience, deep pockets and a willingness to place risky bets. Companies will need to achieve genuine breakthroughs to tackle a wide range of conditions. Nutraceuticals is likely to benefit from the trend of personalized medicine, therefore using and creating technology which aids this movement will be key.

Consumer companies are already experts in collecting data, analyzing behavior and lifestyle, and using the information to target their customers with tailored offers based on their shopping habits. In 2013 Tesco unveiled plans to use their Clubcard data to tackle obesity, by looking at shoppers' baskets and tailoring suggestions for healthier eating¹. Consumer companies have the intelligence available to personalize dietary advice, and with prudent partnerships, pharmaceutical companies may be able to personalize over-the-counter nutraceutical products to supplement consumer lifestyles.

Personalization is also exemplified by genomics, which tailors treatments closely to an individual's genetic profile. Epigenetics and nutrigenomics recognize that each individual has different nutritional requirements and responds to food in different ways. By linking diet to the genome it may be possible to not only boost health, but also reduce the chance of developing conditions such as cardiovascular disease, obesity, diabetes and inflammatory bowel disease. Physicians will be able to predict patients' reactions to different compounds, and - with the help of pharmaceuticals companies – devise holistic regimes incorporating things like behavioral change and biofeedback. Consumers are already being given the opportunity to take this into their own hands, with personalized DNA and genomics reports widely available. Pharmaceutical companies must establish a route to target these health conscious individuals with personalized solutions.

Using technology, foods themselves will also become healthier. The (often controversial) use of genetic modification and marker-assisted selection is helping farmers breed stronger, fortified, pest and disease-resistant crops, such as vitamin A-enriched 'golden rice' and oilseeds containing 'healthier' oil. Nutraceuticals may seem too pricey for emerging economies, but they are the prime beneficiaries of these innovations, where programs such as the non-profit HarvestPlus² are using biofortification to produce crops containing higher amounts of vitamins and minerals.

Compliant marketing

The market for nutraceuticals is not global, and any company that fails to acknowledge this is likely to fail. One reason is that consumers cannot agree whether nutraceuticals are food or drugs, and they are highly suspicious of exaggerated health claims. Another is that each country regulates nutraceuticals differently. In the EU, any product that claims to be a nutraceutical has to be certified first by the European Food Safety Authority, which tests the product to see whether it lives up to its claims. Canada operates a similarly demanding process. In both cases, only a small proportion of claims are approved.

In the U.S. and Japan, by contrast, nutraceuticals do not have to pass stringent government tests, as long as they do not claim to treat or prevent a specific disease. Japan was the first country to recognize functional food officially, in 1984³, and has the world's second largest nutraceuticals market. In the U.S., the largest market, a company can make a claim about a structure or function – for example that pomegranate juice, helps the heart and blood vessels⁴. But for a label to assert that it "prevents cardiovascular disease" requires the approval of the FDA.

The lack of harmonized rules means that companies must adapt their marketing strategies to the regulations of each country, varying the nutritional claims and even the ingredients, depending on the rules and consumer preferences. This calls for sophisticated and supple logistics to supply the precise ingredients and print the appropriate packaging. The most successful exponents invest considerable resources in lobbying and engaging with the various food and supplement bodies at a national and, where necessary, regional level, to prepare for changes ahead of any new laws.

Government policies don't just deter; they can sometimes help to promote the consumption of functional foods as a by-product of national public education campaigns for healthy eating. They can also steer the market towards more responsible offerings, by applying schemes such as so-called 'fat taxes' on products containing excessive amounts of sugar or fat. Both food and pharmaceuticals companies are accustomed to dealing with complex regulations, but unless projected sales justify the effort, they have often dropped nutraceutical products in a given market, or withdrawn them if the rules change.

¹ http://www.thegrocer.co.uk/channels/supermarkets/tesco/tesco-reveals-clubcard-healthier-eating-plans/343589.article?utm_source=rss_feed&utm_medium=rss&utm_campaign=rss&redirCanon=1

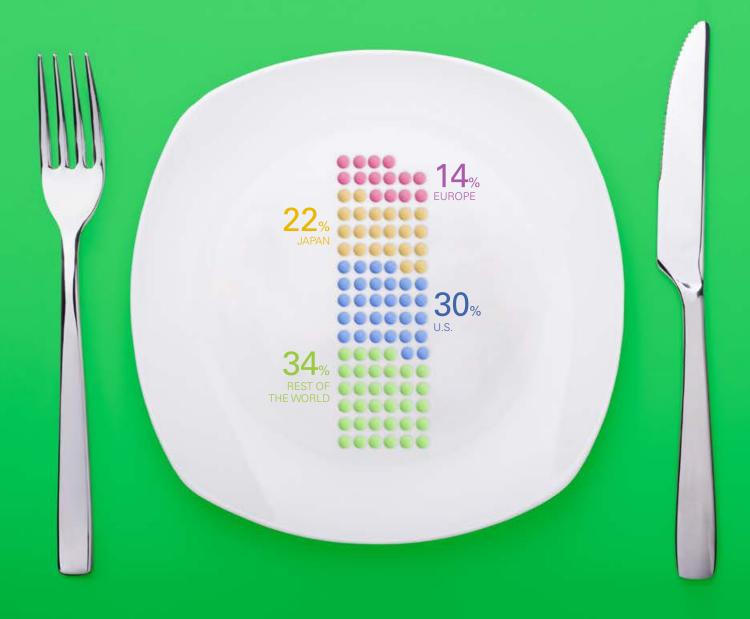
² http://www.harvestplus.org/content/faq

³ http://www.medicinalfoodnews.com/vol01/issue2/japan

⁴ https://www.drfuhrman.com/library/article19.aspx

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Global nutraceuticals market by country/regional share¹



The annual global nutraceuticals market is expected to be worth US\$250 billion by 2018

1 Euromonitor, 2010 figures.

A snapshot of global regulations

United States

In the U.S., nutraceuticals mainly come under the category of vitamins and dietary supplements. A range of regulations apply, notably the Dietary Supplement Health and Education Act (DSHEA) from 1994, which covers dietary supplements, the Federal Food Drug and Cosmetic Act, which covers all foods and food additives, and Good Manufacturing Practice regulations from 2007. Under these the manufacturer:

- is responsible for ensuring the safety of supplements it makes or distributes
- must make no false or misleading claims
- cannot claim the product will diagnose, cure, mitigate, treat or prevent a disease
- must notify the FDA if wishing to use any ingredient not sold before October 15 1994, with the notification containing information the manufacturer/distributor has used to certify the product's safety
- must guarantee the identity, purity, strength and composition of their supplements (deadline for compliance by all manufacturers was June 2010).

In 1988 the FDA awarded 'orphan drug' status to medical foods to encourage their development and some U.S. healthcare plans reimburse medical foods.

EU

A complex range of regulations applies to nutraceuticals in the EU, depending on the product type. These are mainly overseen by the European Food Safety Authority (EFSA), which also evaluates claims and has a public Register of Nutrition and Health Claims. If a product is not on this certified list it cannot be used until approved for inclusion following detailed scientific testing by the company and subsequent review by the EFSA. The EFSA also sets maximum and minimum levels of ingredients to be added to supplements. Labels cannot contain claims that their product will diagnose, cure, mitigate, treat or prevent a disease; nutrition and health claims must be authorized at an EU level.

Between 2008 and 2011 the EFSA evaluated 2,758 food-related general health claims to see if they were supported by scientific evidence. Only around 10 percent of the claims could be substantiated.

China

China has a lengthy and costly registration process, with three main entities involved in policing the industry. The State Food and Drug Administration (SFDA) is in charge of dietary supplements and registration. The Ministry of Health (MOH), oversees the SFDA and the approval of new novel food ingredients. Finally, the Administration of Quality Supervision Inspection and Quarantine (AQSIQ) controls all the imports and exports.

Japan

Foods with nutrient function claims are not heavily regulated and simply must satisfy the standards for the minimum and maximum daily levels of twelve vitamins and five minerals. Foods for specified health uses (FOSHU) require pre-marketing approval, and refer to products containing dietary ingredients that have reported beneficial physiological effects and promote health. Disease risk reduction claims are not allowed.

India

The manufacture, storage, distribution, sale and import of nutraceuticals in India are regulated under the Food Safety and Standards Act (FSSA). The required manufacturing oversight is less strong than for pharmaceuticals, which may impact Indian producers' ability to produce nutraceuticals for export.

Supple supply chains

Technological prowess and marketing smarts are not all that's required to build a nutraceuticals powerhouse. Manufacturers of functional foods must also pay close attention to every stage in the supply chain. With increasing consumer concerns about food safety, the quality of the raw materials used to create nutraceutical supplements have come under intense scrutiny, so companies must consider carefully how to access and assure supplies of essential ingredients or flavorings.

In the U.S., nutraceutical companies collect detailed information about suppliers using the Standardized Information on Dietary Ingredients protocol¹, which provides data on the (wild or cultivated) sources of ingredients, the methods of agricultural process and manufacture, and of sterilization. Supply chain risks can be high: sun-dried materials, for example, may be subject to the growth of mold or even toxins. A number of recent acquisitions of food and beverage companies are aimed at securing stable, high-quality supplies of raw materials. Having acquired nutritional supplements manufacturer Complan Food UK in 2011², for example, Danone purchased a 40 percent stake in Kenya's Brookside Dairy in 2014, which has around 140,000 milk farms in East Africa³. Such vertical integration not only gives greater certainty of supply; it also lays a foundation for developing new uses of existing materials, or to produce new, related ingredients.

Consumer perception is also essential. Starbucks, the coffee company, had to reformulate some of their beverages when consumers reacted to the use of 'natural cochineal extract'. This extract, derived from an insect, was used to provide their products a red color. Cochineal was replaced with lycopene, a natural, tomato-based extract, in the strawberry sauce (base) used in their Strawberries & Crème Frappuccino[®] blended beverage and Strawberry Banana Smoothie.

Tomorrow's success stories: The big players must show patience when investing in start-ups. Many innovative young companies are passionate about nutrition and value their independence. They may resist attempts to be subsumed into a bigger corporate environment, irrespective of the potential financial rewards. In such instances, investors may have to settle for a smaller share.

¹ http://www.npainfo.org/NPA/Communications/SIDI.aspx

² http://www.pmmireports.org/pmmi/2011/07/01/danone-acquires-complan-food-uk/

³ http://www.bloomberg.com/news/2014-07-18/danone-buys-40-of-kenya-s-brookside-to-expand-african-footprint.html



Investing in nutraceuticals

Faced with technological, regulatory and logistical challenges, food and pharmaceuticals companies are taking advantage of the growth of nutraceuticals in different ways. Some are investing in start-ups. Nestle has set up a venture capital fund with the aim of investing in early-stage nutraceuticals businesses. The fund takes varying stakes in these entities and then tries to buy a majority share at a later date, should the start-up prove successful. On the pharmaceuticals side, Alliance Boots (now part of Walgreens Boots Alliance¹, a global pharmacy chain created at the end of 2014) launched a specialized investment fund, B&B Investment Partners, which focuses on small- and medium-sized consumer brand businesses within health, wellness, beauty and personal care. One of its first deals, announced in November 2014, was the US\$30 million acquisition of PhD Nutrition, a leading producer of protein powder and nutrition bars².

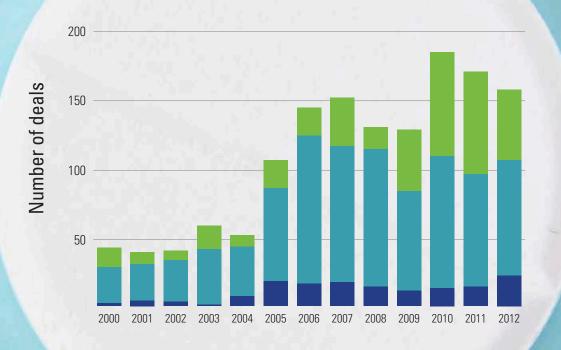
Other companies have been re-balancing their product portfolio, abandoning companies that don't fit their strategy. In 2013, GSK sold its nutritional drinks brands Lucozade and Ribena to Japan's Suntory³. More recently Nestle unloaded its sports nutrition PowerBar brand to cereal maker Post Holdings of the U.S.⁴ in order to focus on a few winning products. Unilever said in July 2014 that it sold its Slim-Fast diet unit to Kainos Capital, a private equity firm⁵. Danone, by contrast, said in December 2014 that it would keep its medical nutrition business, ending months of speculation that it would sell the unit⁶. The sale of product lines creates new opportunities for the acquirer, and the fragmented structure of the nutraceuticals industry suggests that there will be many mergers in the future. In April 2014, Integrity Nutraceuticals and Cornerstone Research & Development merged⁷, combining the former's capability in the manufacture of powder and capsule products with the latter's production of vitamin supplements. In June 2014, Spanish pharmaceuticals multinational Laboratorio Reig Jofre merged with nutritional supplements specialist Natraceutical⁸. The new entity plans to sell its sciencebased nutritional products through its medical channels, although there is no apparent move to enter consumer markets.

Such mergers are small in comparison with the size of the global nutraceuticals market, but they are a harbinger of bigger transactions to come. It only takes one sizeable acquisition to change the dynamics of the industry, and then other big companies in the field will be forced to respond. In a rapidly changing market, it may be better to take the initiative rather than wait for others to make their move. Whether or not the first company to move, deal making skills of a high order are needed to gain the advantage, as companies scramble for the choicest assets.



- B&B Investment Partners flexes muscles with PhD Nutrition deal, City A.M., 17 November 2014
- https://www.gsk.com.au/media-centre_detail.aspx?view=637 http://www.nestle.com/media/pressreleases/allpressreleases/nestle-sells-power
- http://www.uniever.com/mediacentre/pressre/aases/2014/1/inieversellsSlimEasttoKainosCapital.asp
- http://www.ft.com/intl/cms/s/0/37f5b7aa-8154-11e4-b956-00144feabdc0.html#axzz3OdO0fJS0
- 8 http:///patraceutical.com/images/descargas/eng/investors/relevant_facts/2014-6-26-HR-de-NdP-Fusion-NTC-I_R_l-ing-def.pd
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Nutraceuticals M&A on the rise¹

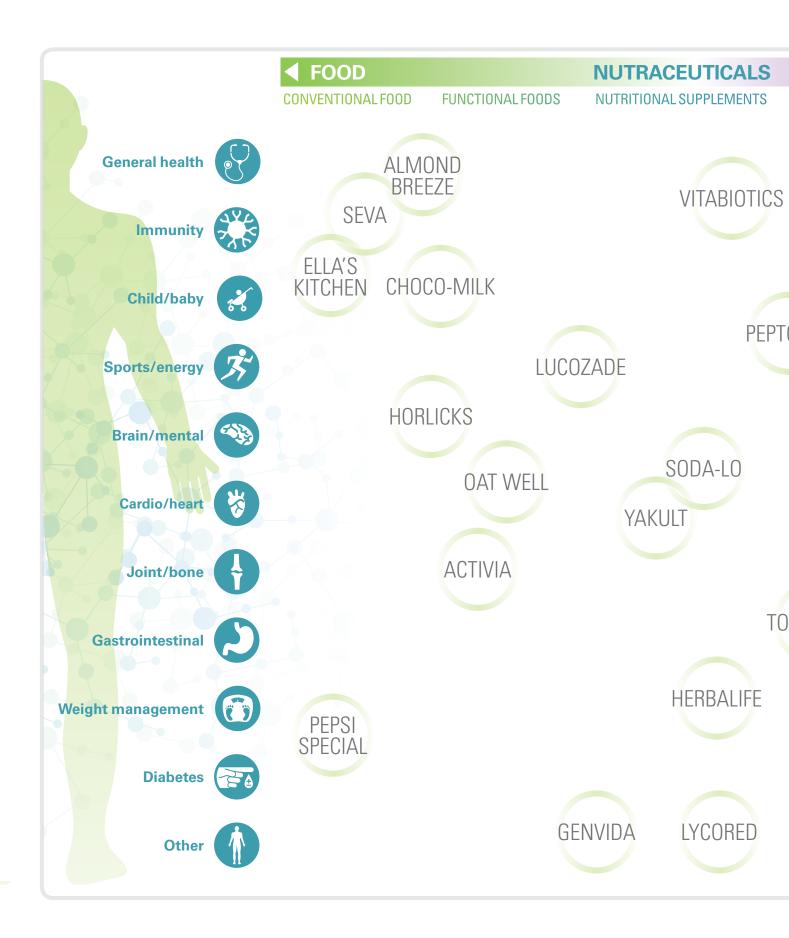


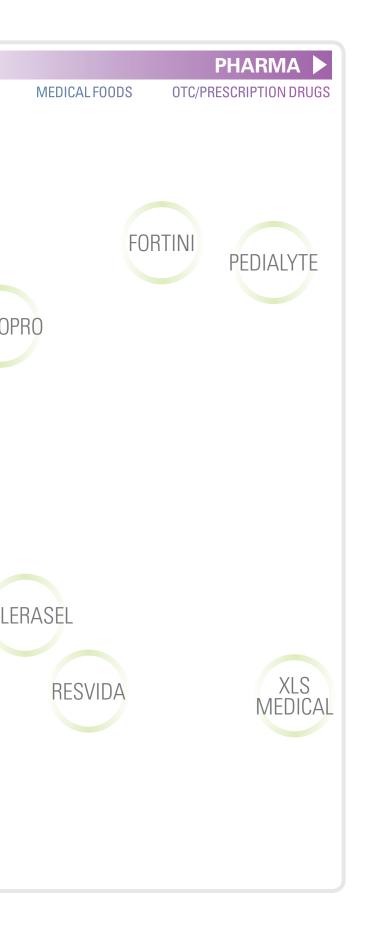
IPOs of nutraceutical companies

Private nutraceutical companies acquired/merged

Public nutraceutical companies acquired/merged

Sector Report, Nutraceuticals Industry, Bourne Partners, April 2013.





RESHAPING NUTRACEUTICALS

Nutraceuticals offers opportunities for pharmaceuticals companies to make their products more consumer-oriented, and for food producers to create brands with a medical image. Adding vitamin supplements or omega-3 could potentially transform a mainstream food substance, while brands traditionally associated with pills could broaden into drinks and snack bars.

Yakult: From food to health

- Beneficial health claims but does not purport to be a cure
- Branded with science and research and medically manufactured
- Set up a microbiological research center looking into probiotics
- Published research papers to demonstrate health benefit
- Began as a consumer 'healthy drink' and is now prescribed by physicians (although still available over the counter)

Accera ('Axona'): From health to food

- Medical claims about metabolism of sugars in the brain
- Associated itself with a specific medical condition: Alzheimer's
- Branded and aligned to scientific evidence
- Prescription only
- FDA warning due to regulatory uncertainty over medical claims

These examples show that innovation is coming from both directions, so successful nutraceutical companies will have to keep their eyes on competitors from both food and pharmaceuticals. Neither industry has sufficient advantages to corner this market; the field is open.

Characteristics of success: Daring to win

To succeed in the brave new world of nutraceuticals, KPMG believes that companies will have to excel in six areas:

> **Technology** – Personalized healthcare is likely to lead to a proliferation of nutraceutical products. Companies will have to place strategic bets on technological breakthroughs to achieve results.

Product strategy – Only the best product strategists are going to make a profit by developing a powerful portfolio of technologies and brands. Blockbusters may be few and far between.

3

Regulation – Regulations around nutraceuticals vary from one country to another and are changing all the time. Manufacturers will have to work closely with governments to anticipate market opportunities that arise when the rules are altered. Marketing – Consumer tastes are likely to be fickle in the field of nutraceuticals. Successful companies will have to develop a highly nuanced global marketing campaign that can exploit economies of scale while adapting to national preferences.

> Supply chain – As researchers explore evermore exotic locales for 'miracle' ingredients, only the most flexible supply chain is going to produce the goods. Avoid high risks by paying close attention to each stage of the chain.

Deal-making – Companies may be able to make up for their weaknesses in certain areas by being quick and decisive corporate dealmakers. They can put together a strong product portfolio through a program of acquisitions and divestments. Speed will be of the essence.

Success in the nutraceuticals market will depend on an ability to take the long view while adeptly seizing short-term opportunities as they arise.

KPMG's nutraceutical credentials

KPMG's global network of member firms work with some of the world's biggest companies across the pharmaceuticals, food and nutraceuticals sectors and can help you create an effective strategy for this fast-growing market. Our expertise spans key areas such as product management, R&D innovation, sales and marketing, market planning, mergers and acquisitions, and joint ventures. We help clients with issues such as:

- managing a product lifecycle
- assessing risks across an R&D portfolio
- building research partnerships with academia and other specialists
- structuring and incentivizing sales and marketing teams
- new market entry planning
- planning, funding and implementing mergers and acquisitions, including financial due diligence.

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