

DIETARY SUPPLEMENTS MARKET: EXECUTIVE SUMMARY

MARKET OVERVIEW. The dietary supplements market is **large and growing rapidly**. The global market – valued at \$133.1 billion in 2016 – is projected to see tremendous growth and reach \$220 billion by 2021 and \$252 billion in 2025, with the U.S., China, and India accounting for the largest shares. Sports supplements have seen the fastest growth (8.3%), followed by the practitioner market (8%), herbal supplements (6.8%) and vitamins (4.6%).

MARKET SEGMENTATION. The dietary supplements market can be segmented by form, application, ingredient, end use, distribution channel, and region. **Forms** include soft gels, confectionary products, pharmacy products, powders, and liquids. **By application**, divisions are weight loss, sports nutrition, general well-being, immune and digestive health, bone and joint health, heart health, and beauty supplements. **By ingredients**, the market divides into vitamins & minerals, amino acids, botanical supplements, and other ingredients. **End users** are men, women, senior citizens, children, and others. **Distribution channels** are pharmacies, health and beauty stores, supermarkets, internet, and direct sales. Major **regions** are North America, Latin America, Europe, Asia-Pacific, and the Middle East and Africa.

DRIVERS OF MARKET TRENDS. The dietary supplements market has been shaped by critical technological, social and regulatory shifts. **First, the growing population of senior citizens** around the world has caused a shift in healthcare spending. **Second, a focus on preventative healthcare** has been critical to market growth, as heightened consumer awareness has increased the effectiveness of manufacturers' marketing efforts. **Third, an increase in self-directed care** has shaped the markets. With the rise of the internet and the increasing volatility of the healthcare insurance market, more consumers seek help online and become increasingly interested in personalized medicine and care. **Fourth, ease of access has improved.** Although a few companies dominate the market, the distribution channels are varied, and the internet is reducing barriers to access. **Fifth, regulatory pressure** has changed. As the market grows, there will be tightening pressure from government agencies and an increase in oversight. The FDA has upped enforcement of dietary violations, which will impact clinical trials and research.

KEY ISSUES. *Supplements vs. drugs and food additives.* Definitions are a key issue: how do you define a dietary supplement, how does it differ from a drug, and how does a dietary ingredient in a supplement differ from a food additive in a conventional food? The pre-market approval process for direct food additives and drugs is expensive. It also requires manufacturers to test the product's safety and effectiveness and then to be reviewed by FDA before new products are introduced into the marketplace. Under the Dietary Supplement Health and Education Act (DSHEA) of 1994, dietary supplement ingredients may be sold without undergoing a formal FDA approval process.

Safety of ingredients. A company wishing to market a new dietary supplement ingredient must submit to FDA a notification including information showing that the ingredient “will reasonably be expected to be safe”. Since passage of DSHEA, FDA has identified several problems and manufacturers have conducted recalls to remove potentially dangerous products from the market. In addition, state and local governments may set more stringent laws and regulations for the sale of dietary supplements. Since 1993, a system has been in place to report to FDA problems related to dietary supplements, infant formulas, and medical foods.

Classification and labeling. Dietary supplements are classified as food products, but DSHEA stipulates that such products must be labeled as “dietary supplements” and be sold in the form of pills, capsules, tablets, gel-caps, liquids, powders, or other forms, and not be represented for use as conventional foods. Supplements also cannot be marketed as the only item in a meal or diet. The label must list all dietary ingredients and the Daily Values (DV) of the amounts contained in a serving. If no DV has been established for a dietary ingredient, this must be indicated.

Health claims vs. nutritional support claims. Health claims are specifically defined under NLEA as statements that characterize the relationship between a food substance and a specific disease or health-related condition, and which are based on significant scientific agreement. DSHEA permits four types of claims to appear on supplement labels. These claims can be distinguished from real health claims because they are not permitted to state or imply a link between a supplement and the treatment, diagnosis, cure or prevention of a disease. In November 1998, the Federal Trade Commission (FTC, 1998) issued for the industry an advertising guide on dietary supplements that clarified truthful claims with respect to advertising. The guide states that dietary supplement manufacturers must back up explicit claims and implied benefits made for their products.

ALLIANCES, COLLABORATION & INITIATIVES. The **Global Retailer and Manufacturer Alliance (GRMA)**, convened by NSF International, is an organization with industry support from more than 30 major retailers, who are developing a GMP auditing standard for dietary supplements based on criteria from the Food Safety Modernization Act (FSMA). The **Dietary Supplements Quality Collaborative**, convened by USP, is a collaborative aimed at improving the quality and safety of products marketed as dietary supplements, and includes consumer representatives, supplement manufacturers, public health and patient advocacy groups, and others. DSQC is focused on bolstering FDA's authority and resources and the responsibilities of participants in the supply chain. The **Supplement Safety & Compliance Initiative**, convened by NPA, is a retailer-led initiative to provide benchmarks, share best practices, and enforcement safety standards throughout the entire dietary supplement supply chain.

INDUSTRY ASSOCIATIONS / STANDARDS DEVELOPERS. **U.S. Pharmacopeia (USP)** establishes written (documentary) and physical (reference) standards for medicines, food ingredients, dietary supplement products, and ingredients. These standards are used by regulatory agencies and manufacturers to help to ensure that these products are of the appropriate identity, as well as strength, quality, purity, and consistency. **American Herbal Pharmacopoeia (AHP)** develops qualitative and therapeutic monographs on botanicals, including many of the Ayurvedic, Chinese, and Western herbs most frequently used in the United States. **AOAC International** is a globally recognized, independent, third party, association and voluntary consensus standards developing organization and the forum for finding appropriate science-based solutions through the development of microbiological and chemical standards. **Underwriters Laboratories (UL)** is a global safety science company and certification firm. The **Natural Products Association** advocates for the SSCI. **NSF International** convened the **GRMA** and is close to finalizing its dietary supplements standards, and the **British Retail Consortium (BRC)** has developed a consumer product standard which includes dietary supplements. **SQF Institute** is recognized by retailers and foodservice providers around the world who require a rigorous, credible food safety management system. The SQF Program is recognized by the Global Food Safety Initiative (GFSI) and links primary production certification to food manufacturing, distribution and agent/broker management certification

The **Council for Responsible Nutrition (CRN)** is a trade association representing 150+ dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. The **United Natural Products Alliance (UNPA)** represents more than 100 natural products, dietary supplement, and related service companies. The **Consumer Healthcare Products Association (CHPA)** is a trade association representing manufacturers and marketers of over-the-counter (OTC) medicines and dietary supplement. The **American Herbal Products Association (AHPA)** comprises more than 350 companies, including manufacturers and marketers of botanical and herbal products. The **Natural Factors Farm** has been sponsored by the **Natural Food Merchandiser (NFM)**, a leader in the healthy lifestyle products industry. **Independent Natural Food Retailers Association (INFRA)** is known to the organic and natural supply chain and its NGO partners. **Natural Grocers** by Vitamin Cottage is a rapidly expanding specialty retailer of natural and organic groceries and dietary supplements.

MAJOR COMPANIES. Amway, Bayer, Abbott Labs, Archer Daniels Midland Company, Arkopharma Labs, The Himalaya Drug Company, GlaxoSmithKline, Glanbia, Nestle, Pfizer, DSM, BASF, Yakult, Danone, American Health, and Bayer HealthCare.