Promoting health by better food intake is essential for public health. Active research and product development in the food category stimulates introducing various health foods/dietary supplements into the market. These products are well-recognized and believed to be useful by the public. They have gained popularity in many countries, and recent research has found that more than half of the population uses health foods/dietary supplements in the US (1). While a lot of information is available, especially through the Internet nowadays, no matter whether reliable or not, consumers are not completely confident about how to choose products. Unlike prescribed medicine, consumers use their own judgment to choose health foods without clear information most of the time. Consumers may be able to acquire health benefits from the products in this uncertain way, but they may also suffer from unnecessary spending and suffer unwanted effects through misunderstanding due to insufficient information. Therefore, consumer education is very important, as ensuring safety takes priority over efficacy.

One of the effective ways to solve consumer confusion is to organize food label requirements. However, the food labeling system is complicated and many consumers do not understand it correctly. Some industries do not respect requirements, and they may use ingredients which may not have enough information on their efficacy and safety. With the increasing use of health foods, it is important for consumers to ensure an appropriate use of these products. The biggest concern in health food would be that some consumers incorrectly use health food/dietary supplement as medicine. Needless to say, these are quite different materials and controlled in a different way; medication targets the cure or prevention of diseases, and ease of symptoms. On the other hand, health foods work in a way to prevent uncomfortable health conditions. It is clearly shown that daily lifestyle-related diseases, such as metabolic syndrome, are strongly related to food intake. Therefore, lifestyle change could be one of the effective ways to reduce the risk of unhealthy conditions.

**United States**

Misleading information is one of the major factors to confuse consumers. The food labeling system has a role in providing proper information to consumers when they choose products. In the US, the Dietary Supplement Health and Education Act (DSHEA) (2) was established with consumer education as one of major purposes along with safety and quality. Dietary supplements in the US are classified under foods. After the DSHEA was established in 1994, the supplement market grew by about 4 times to reach over $32 billion as of 2012. One of the major reasons for this market expansion is that consumers can recognize functions of the supplements by the structure/function (S/F) claims. S/F claims must not be false or misleading, and must be based upon reliable scientific evidence, especially clinical studies. At the same time, disclaimers must be shown on the package, which are “These statements have not been evaluated by the Food and Drug Administration (FDA). These products are not intended to diagnose, treat, cure or prevent any disease.” Both the FDA and Federal Trade Commission (FTC) are responsible for label claims and advertisement of dietary supplements. S/F claims are not medical claims, but these may have impact on people’s mindset to be healthier. Recent research shows utilizing dietary supplements in 4 major areas with 10 popular ingredients could hypothetically reduce medical costs by over $50 billion in the US in the period of 2013–2020. Predicted fewer health problems and reduced medical cost information will further increase awareness of supplement usage and thus may raise quality of life. These may reduce the medical cost significantly, if the products are used appropriately with sufficient consumer education.

**Key Words** dietary supplements, health foods, US labeling system

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1) Safety

Assurance of consumer safety is the first priority. Product safety information must be obtained by assuring the reporting of product safety studies. The DSHEA allows consumers to select products based on multiple inputs. Since the DSHEA passed, there has been a very low incidence of safety concerns.

In addition, as a part of consumer protection, a reporting system of post-market adverse effects was established. The industry must actively seek current product information and report all known drug interactions. The US FDA has used adverse event reports (AERs) for some consumer protection actions (e.g., inspections and warning letters), but may be able to expand their use. FDA officials said that most AERs do not initiate or support such actions, because it is difficult to establish causality between the product and the health problem based on the limited information in an AER. When interpreting AERs, FDA officials said that it is important to understand that an AER by itself does not demonstrate a causal relationship between the dietary supplement and the reported health problem. Rather, the officials said that there are several other factors that must be considered to determine causality, such as the role of other products consumed at the same time and preexisting health conditions. As shown in Fig. 1, the vast majority of the supplements identified in the AERs numbering 5,248 were a combination of different types of ingredients, such as vitamins and minerals.

Regarding supplement-drug interactions, it is not realistic to examine all possible drug interactions, so mandating drug interaction data should be avoided. However, collecting and sharing such information from the database would be useful for consumers and regulators. In the US, drug marketers are responsible for confirming any contraindications with food.

2) Structure/function claims

Currently, the function and effect of a drug under the Pharmaceutical Affairs Law are exclusively applied to the drug. The regulatory system must not deter a patient with a severe symptom from seeing a doctor. At the same time, there are various symptoms that can be improved by the effective use of health foods/dietary supplements. S/F claims are not medical claims, but these may have impact on people’s mindset to be healthier. With regard to S/F claims, policies distinguish dietary supplements from drugs while educating the consumer and developing the market. The following summarizes claims and policies as outlined by the DSHEA:

- It is not permitted to use drug-like descriptions such as “diagnose,” “prevent,” “treat,” “mitigate” or “cure.”
- Words such as “stimulate,” “support,” “maintain,” “adjust” or “promote” are permitted if they do not imply an effect on disease, as these descriptions are easy for consumers to understand.
- Generally recognized conditions that are not severe and that follow natural body changes may be treated as a non-disease.
- Even though individual words may imply disease diagnosis, treatment, recovery and/or prevention, the overall statement should be considered. For example, terms related to a physiological reaction, such as “relieves temporary joint inflammation caused by excessive exercise” or “supports a healthy immune response” should be permitted if they can be substantiated without claiming to treat the condition.

Claims which are equivalent to a drug effect on symptoms that are clearly not defined as a disease are permitted. Ambiguous symptoms that are often related to function or structure conditions of the body are also allowed. Since the purpose of dietary supplements is to act on the structure and function of the body, words such as “fatigue,” “strength,” “tonic,” “appetite,” “aging,” or “immune function” should be permitted when devising label descriptions. For dietary supplements, the specific claims should not be regulated but should be substantiated with scientific data. This would prevent any economic loss that would be caused by completely banning the claim yet would educate the consumer by making the supporting information available. All claims which are approved based on the efficacy of a nutrient should be permitted. In addition, for products containing these nutrients, the inclusion of the efficacy for additional ingredients should be permitted as long as the efficacy is substantiated. The wording should not be regulated, but should be considered based on the level of substantiation of the product claims.

The FOSHU approval system in Japan evaluates the final product in association with one ingredient. As it costs too much and takes too long a time to obtain an approval, it is not suitable for mid- and small-sized companies. This is the initial thought by the Prime Minister and Cabinet to establish an alternative system to allow functional claims for health foods/dietary supplements in Japan. Ingredients such as various botanical extracts,
whose functional components are not clearly identified, are often found to have a physiological efficacy and must be considered under the new regulations.

Grading levels of functional claims of dietary supplements using a stepwise categorization has been introduced in several jurisdictions. How implementation of this grading system will be carried out is still unknown, however, and it is not necessarily recommended, as the health food/dietary supplement industry is not motivated by low-level qualifications.

Scientific substantiation of product claims found in scientific databases such as Medline, Chemical Abstract and others should be utilized. In addition, in-house data or research is allowed as part of product substantiation. Studies conducted outside of the country are also recognized, unless there is scientific evidence to suggest that the study results would be different in Japan’s population. There is no clear evidence that overseas research results cannot be expanded to be utilized in a specific population. However, the difference in the impact may be much larger in one population than that in a different population, as indicated in the references (4–6). Many current product claims have been substantiated based on western research, and differences among races or gene diversity must be considered in future research. Realistically, current reports in relevant databases must be utilized to substantiate product claims and the scientific data should not be limited to a single population.

Medical Cost Reduction

According to recent scientific research in the United States, medical costs might be decreased by over $50 billion in the US in the period of 2013–2020 by using dietary supplements in 4 major areas with 10 popular ingredients (7). These results are encouraging for both health policies and consumer health, but further research is needed, especially for predominantly Japanese health issues. Predicted fewer health problems and reduced medical cost information will further increase awareness of supplement usage and thus may raise quality of life. These may reduce the medical cost significantly, if the products are used appropriately with sufficient consumer education.

Prospective Industry Development

If health foods/dietary supplements carry functional claims, they would contribute to the health of the population and to the economic growth of the country. This outcome is included in Prime Minister Abe’s economic recovery plan in Japan. The US dietary supplement industry quadrupled in size over the past 20 y. Giving consumers confidence in product safety will position the industry to grow.

Proper regulations ensure the safety and functionality of health foods/dietary supplements based upon the industry’s self-monitoring responsibilities. The industry should utilize its own self-certification system including quality control of manufacturing processes, subject to its following international best practices. This system has been successful in the US where it has been accepted by agencies. Considering the exportation of products to foreign countries, overseas jurisdictions are establishing common manufacturing guidelines (GMP for dietary supplements and HACCP for health foods). Only Japan regulates the quality of health foods under the Food Sanitation Act rather than under these global manufacturing guidelines. If the quality of health foods/dietary supplements is not assured by adopting global standards, the domestic industry, which does not currently conform to the global GMP standard, will be at a significant disadvantage for exportation. To promote global trade, a globally standardized GMP system must be established. It will also protect consumers from the entry into the Japanese market of poor quality supplements. Recently, the Ministry of Health, Labor, and Welfare conducted a survey of domestic GMP compliance, and these results should be disclosed. Establishing quality GMP compliance to the global standard is important in many aspects and a deadline for such compliance must be set. Adherence to this global GMP, especially the current GMP (cGMP) should suffice for quality control of the products for sale and do so without requiring an analysis of specific ingredients.

Conclusion

Health foods/dietary supplements could be a good addition to a balanced diet and lifestyle to help people in healthy condition. By establishing safety, quality and efficacy, these products would be accepted by the public and legislatures. That will help reduce medical costs and raise awareness of a healthy lifestyle among the public.

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