

Original Article**Gaps in the information shared on consumer healthcare products**Makiko Hayashi¹, Shintaro Sengoku², Sakuo Hoshi^{1,*}, Hiromichi Kimura¹¹ *Pharmaco-Business Innovation Laboratory, Graduate School of Pharmaceutical Science, The University of Tokyo, Tokyo, Japan;*² *Innovation Management Science Laboratory, The University of Kyoto, Kyoto, Japan.*

ABSTRACT: We conducted a questionnaire survey of visitors to the Japan Drugstore Show 2006 and an additional questionnaire survey of pharmacists in 2008 to ascertain the current information gaps between consumers and manufacturers of consumer healthcare products (CHPs). Three main gaps were apparent: first was a gap between information that consumers wanted to receive and information that was widely disclosed by manufacturers of CHPs, second was a gap between the advisors whom consumers regarded as appropriate and the advisors who consumers had actually consulted, and a gap between what consumers expect pharmacists to know and pharmacists' actual knowledge. Manufacturers' efforts alone will not be able to close these gaps because of the number of regulations. Thus, a new social system should be constructed to supply adequate information on CHPs and consumers should enjoy free access to this information.

Keywords: Consumer healthcare product, information sharing, gap

1. Introduction

Recently, more Japanese have become conscious of their health. The rapid aging of Japanese society unlike that in any other country may be a driving force behind these health concerns. A new health examination focusing on metabolic syndrome that started in April 2008 may also affect concerns about health. As a result, the market for health-related products has grown rapidly. The Ministry of Economy, Trade and Industry (METI) has estimated that the market for consumer healthcare products (CHPs) had reached 1.3 trillion yen in 2000 and will expand to about 3.2 trillion yen

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in 2010 (1). CHPs have now become a popular part of daily life. However, such a rapid growth in CHPs also causes trouble for consumers. Some CHPs have evidence indicating their efficacy at improving health, but others have dubious efficacy, safety, and quality. The confusion over foods for specific health uses, *i.e.* "health foods," may be one factor for this trouble. That is, foods for specific health uses are regulated by the METI, while "health foods" (Table 1) are simply "food," so permission, approval, and notification for their labeling claims are not regulated by the METI. Therefore, each consumer must obtain information on "health foods" and evaluate their efficacy, safety, and quality individually. That said, only a few consumers appear able to evaluate "health foods" correctly on the basis of adequate information. Most consumers seem to be influenced just by information deluging them without being able to evaluate those foods.

The Internet now allows free, instant access to news sources around the world with regard to CHPs. That said, some information seems to have dubious reliability and to contain exaggerated advertisements. Such information may cause consumer misunderstanding with regard to the efficacy, safety, and quality of CHPs. The following are examples of confusion-causing statements: "Some diseases can be treated by some CHPs," "The more we take CHPs, the more effective CHPs are," "CHPs cannot be harmful to humans because they are health food," and "All CHPs are officially guaranteed to be safe because they are marketed as health foods." Such statements are why some CHPs actually cause problems with consumer health.

Under these circumstances, the Ministry of Health, Labour and Welfare (MHLW) enhanced the regulatory and guidance systems for CHPs (2-7). In 2002, the MHLW issued a notice to promote the training of advisory personnel with special knowledge about CHPs (8). In the same year, the National Institute of Health and Nutrition, an "independent policy corporation," established a public qualification system for Nutrition Representatives. The MHLW has also reviewed systems for regulating CHPs since 2003 and established guidelines to manage the safety of CHPs in tablets or capsules in 2005 (7). These guidelines are expected to improve CHPs manufacturers' risk management and to

Table 1. Category of consumer healthcare products

Drugs	Foods		
	Foods with Health Claims		General Foods
Drug			
Quasi-drug	Functional Nutritional Foods	Foods for Specific Health Uses	"Health Foods"
	Other		
	Consumer Healthcare Product (CHP)		

A "consumer healthcare product (CHP)" is defined as shown in Table 1 (shown in gray). CHPs include foods with health claims, which include functional nutritional foods and foods for specific health uses, as well as "health foods." Foods for specific health uses are regulated by the MHLW, and functional nutritional foods are officially defined. That said, the words "consumer healthcare product," "health food," and "health foods" are not officially defined.

perhaps also improve consumers' awareness of the risks of CHPs. That said, the rapid growth and expansion of the CHP market of and its rich variety of products, including foreign imports, mean that there should be limitations to regulate the wide variety of CHPs in accordance with the same guidelines.

Thus, the current study surveyed consumers to ascertain problems with CHPs. A questionnaire was distributed at the Japan Drugstore Show 2006, and several gaps in information sharing with regard to CHPs became apparent. An additional questionnaire was distributed among pharmacists in 2008. Another gap in the information sharing with regard to CHPs also became apparent. The results of the surveys are reported here, and a new way to eliminate gaps in information sharing with regard to CHPs is proposed.

2. Materials and Methods

The Japan Drugstore Show 2006 was held on February 11, 2006 at Makuhari in Chiba Prefecture. A questionnaire was distributed to the visitors of the Japan Drugstore Show. The completed survey was collected on the same day. Visitors were asked about (i) their individual attributes (gender, age, and occupation), (ii) their purchase histories with regard to CHPs, (iii) their motives for purchasing CHPs, (iv) the route by which they purchased CHPs, and (v) how they obtained information about CHPs. As a result of that survey, an additional questionnaire was distributed to new pharmacists at Ain Pharmacies, Ltd. on May 12, 2008. The completed survey was collected on the same day. This survey focused on the pharmacists' purchase histories and knowledge of CHPs. Table 1 shows the categories of CHPs.

3. Results

A total of 515 questionnaires was distributed to the visitors of the Japan Drugstore Show held on February 11, 2006 and a total of 501 responses was received, indicating a response rate of 97.3%. Of the 501 respondents, 134 were men (26.7%) and 367 were women (73.3%); 15 were teens (over 15 years old) (3.0%), 82 were in their twenties (16.4%), 156 were in

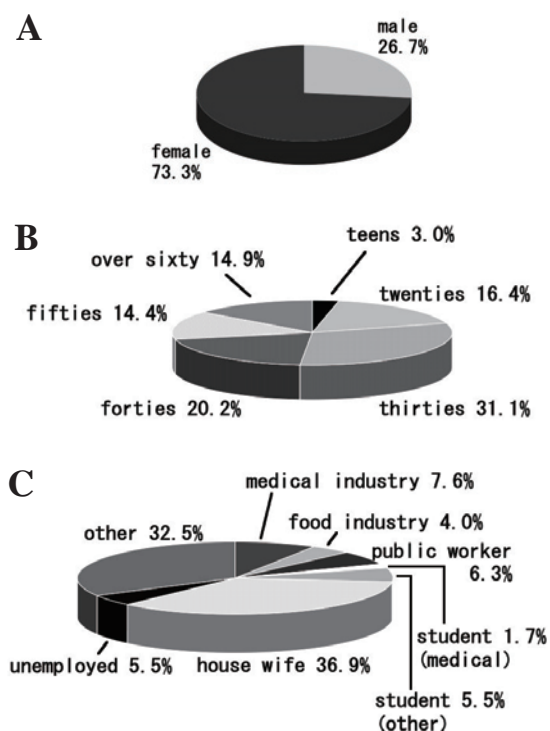


Figure 1. Attributes of respondents. (A) Gender of respondents, (B) Age of respondents, (C) Occupation of respondents. *n* = 501.

their thirties (31.1%), 101 were in their forties (20.2%), 72 were in their fifties (14.4%), and 75 were over sixty (14.9%). Most respondents were housewives (36.9%). Age and occupation distributions are shown in Figure 1.

A total of 28.1% of respondents bought certain CHPs regularly, a total of 17.1% of respondents bought certain CHPs irregularly, a total of 21.5% of respondents bought different CHPs, and a total of 33.3% of respondents did not buy any CHPs (Figure 2). The age and occupation distributions were similar for each group (data not shown). Most people bought CHPs at drugstores and mainly received information about CHPs from drugstores, TV, and the Internet. Manufacturers or manufacturers' web sites were seldom used as sources of information on CHPs (Figure 3).

People mainly consulted with medical doctors, dentists, pharmacists, and other users. They wanted

to consult with advisory personnel though seldom did so (Figure 4). People obtained information on CHPs mainly in regard to the efficacy and safety of specific products or specific components or about the reputations of specific products or specific components (Figure 5). People who bought certain CHPs regularly or irregularly tended to obtain more information about efficacy than people who bought different CHPs or who

did not buy CHPs (data not shown).

A total of 158 questionnaires was additionally distributed to new pharmacists at Ain Pharmacies, Ltd. on May 12, 2008. Of the 158 respondents, 77 were men (48.7%) and 81 were women (51.3%); 153 were in their twenties (96.8%) and 5 were in their thirties (3.2%). A total of 5.2% of respondents bought certain CHPs regularly, a total of 22.4% of respondents bought certain CHPs irregularly, a total of 39.7% of respondents bought different CHPs, and a total of 32.7% of respondents did not buy any CHPs (Figure 6). Though 96.2% of those pharmacists knew the names of CHPs, only 38.0% of the pharmacists could explain the categories of CHPs (data not shown), and only 10.9% indicated that they could explain the effects of CHPs (Figure 7). Those who were able to explain about CHPs obtained their knowledge mainly from lectures at university, followed by TV or magazines (data not shown).

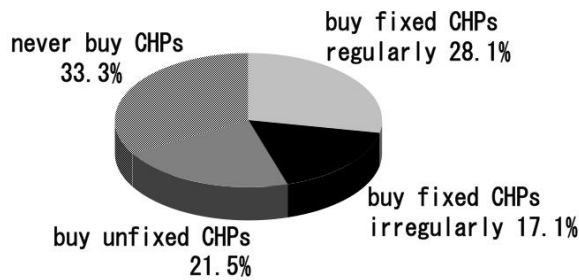


Figure 2. Purchase histories with regard to CHPs. *n* = 501.

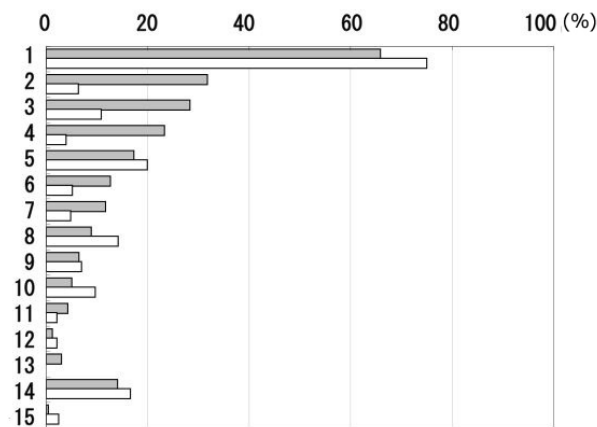


Figure 3. Means of buying CHPs and means of obtaining information on CHPs. □, Buying CHPs (*n* = 324); □, Obtaining information on CHPs (*n* = 496). 1, drugstore; 2, television; 3, Internet; 4, magazine; 5, catalog; 6, hospital/clinic; 7, newspaper; 8, pharmacy; 9, convenience store; 10, speciality store; 11, web site; 12, door-to-door sales; 13, did not receive information; 14, other; 15, no answer.

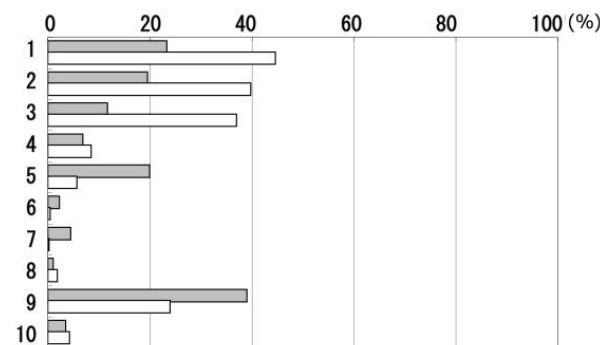


Figure 4. Advisors with regard to CHPs. □, Advisors whom respondents actually consulted (*n* = 481); □, Advisors whom respondents regarded as appropriate (*n* = 477). 1, medical doctor or dentist; 2, pharmacist; 3, advisory personnel; 4, customer service; 5, other user; 6, door-to-door salesperson; 7, entertainer; 8, researcher; 9, other; 10, no answer.

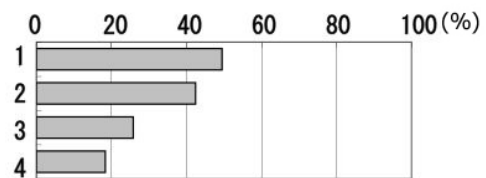


Figure 5. Information that respondents received about CHPs. *n* = 498. 1, efficacy and safety of specific products; 2, efficacy and safety of specific components; 3, reputations of specific products; 4, reputations of specific components.

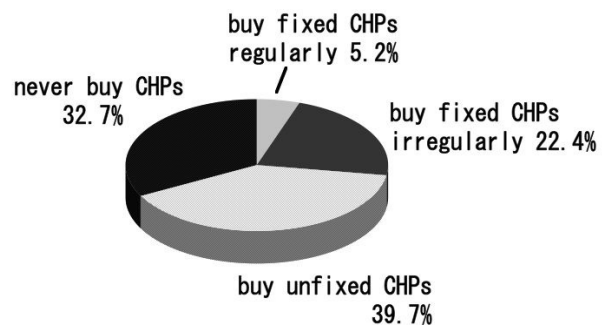


Figure 6. Purchase histories with regard to CHPs (An additional questionnaire survey of pharmacists). *n* = 158.

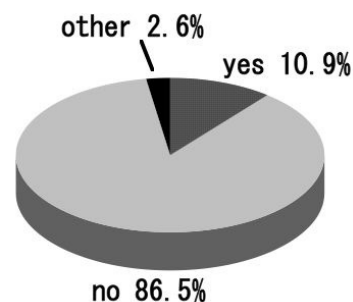


Figure 7. Knowledge of the health effects of CHPs (An additional questionnaire survey of pharmacists). *n* = 158.

4. Discussion

In Japan, an increase in health consciousness is thought to have resulted in a rapid expansion of the market for CHPs, though the market is reaching maturity. That said, the market will expand again as a result of a new mandatory health checkup system (health checkup/health guidance) focusing on metabolic syndrome that was introduced in April 2008. Of course, manufacturers' effort have also contributed to the expansion of the market for CHPs. For example, Calpis Co., Ltd. has spent ten years evaluating the efficacy and safety of Ameal S[®], a food for specific health uses (9). Otsuka Pharmaceutical Co., Ltd. chartered an airplane and conducted simulations on a long-distance international flight to evaluate the health effects of Pocari Sweat[®] in terms of preventing a traveler's thrombosis (economy class syndrome) (9,10). Such manufacturers' efforts should contribute to the prevalence of CHPs and their sound use. That said, there are also a number of reported cases where CHPs caused harm (11).

Many questionnaires have surveyed consumers about their knowledge and use of CHPs (12-15). To the extent known, however, no questionnaires have surveyed consumers about their awareness of CHPs to investigate gaps between consumers and manufacturers. The current study conducted questionnaire surveys regarding CHPs to specifically investigate information gaps between consumers and manufacturers. In this study, CHPs were used under the broad categories shown in Table 1. General foods, drugs, and quasi-drugs were excluded from consideration. This study did not separate CHPs according to the categories shown in Table 1 but considered them as a whole. This was because consumers were considered to be generally unaware of the categories of CHPs themselves. That view was supported by the results of an additional questionnaire for pharmacists. Less than 40% of the pharmacists knew the categories of CHPs (data not shown). Consumer unawareness of the categories of CHPs may also cause gaps in information sharing with regard to CHPs, so a survey separating CHPs by category is planned for the near future.

The current study showed that respondent attributes included different age groups and various occupations, but females, respondents in their thirties, and housewives were dominant (Figure 1). In the actual market, slightly more females buy supplements than males (16,17). Thus, the current study may somewhat highlight the opinions of females. The data showed that about 70% of consumers bought CHPs and about 30% of consumers bought certain CHPs regularly (Figure 2). Consumers bought CHPs mainly at drugstores and obtained information about CHPs mainly at drugstores or from TV and the Internet. Manufacturers' web sites, which were thought to be rich in information, were the least used source (Figure 3). In this study, consumers

were more interested in the "efficacy and safety" of "each CHP" while they were less interested in the "reputations" of "each component of a CHP" (Figure 5). With "health foods", however, manufacturers are restricted in terms of labeling or advertising of health claims by the Pharmaceutical Affairs Law. Only on functional nutritional foods and specific health uses are manufacturers permitted to label or advertise nutrition claims. In short, manufacturers of CHPs are usually unable to provide consumers with information on the health effects of their products. This is why few consumers obtain information directly from manufacturers (Figure 3). Obviously, however, manufacturers of CHPs have the most information on those products. Thus, one can conclude that is a gap between information that consumers want and information that manufacturers can provide. Needless to say, regulations should exist, but manufacturers should be better utilized as resources.

Medical doctors or dentists, pharmacists, and advisory personnel were advisors for CHPs who consumers felt were appropriate for consultation. Of these individuals, advisory personnel should be most appropriate since they have received specific training in CHPs, but advisory personnel were actually consulted the least (Figure 4). Given the great variety of CHPs on the market and the huge amount of information on CHPs deluging consumers, consumers should take advantage of advisory personnel since they are well versed in CHPs. They know, for instance, what each component of a CHP does and its effectiveness and how to use the CHPs and they can provide consumers with correct and adequate information on CHPs. The MHLW is promoting the training of advisory personnel (8), and Japan now has more than ten training systems for advisory personnel, national training systems, public training systems, and private training systems. The results of the current study, however, indicate that consumers consult medical doctors or pharmacists rather than advisory personnel. That may be because advisory personnel are not qualified and not well known. Thus, there is a gap between the advisors that consumers actually consult and the advisors that consumers consider appropriate.

An additional survey showed that about 70% of pharmacists bought some CHPs, which was at almost the same rate as general consumers. Fewer pharmacists regularly bought certain CHPs, *i.e.* 5.2% of pharmacists bought certain CHPs regularly while 28.1% of general consumers did (Figures 2 and 6). Moreover, pharmacists were considered an appropriate source of information by consumers, but in reality only 38.0% of pharmacists knew the categories of CHPs (data not shown) and only 10.9% were able to explain the health effects of CHPs (Figures 4 and 7). Thus, there is a gap between what consumers expect pharmacists to know and pharmacists' actual knowledge.

In conclusion, three gaps were identified. First was the gap between information that consumers want and information that manufacturers can provide, second was the gap between the advisors that consumers actually consulted and the advisors that consumers considered appropriate, and third was the gap between what consumers expected pharmacists to know and pharmacists' actual knowledge. Several steps could be taken to close these gaps. Lectures on CHPs should be included in the curricula of medical and pharmaceutical courses more often and incentives to study CHPs should be given. Qualifications for advisory personnel should be established and standardized. If possible, advisory personnel should be obligatory at drug stores. Qualified salespersons will be obligatory at drug stores, so education of those salespersons in CHPs should be an effective solution.

Needless to say, CHP advertisement should be regulated under the current law. That said, manufacturers may be intentionally flooding the Internet with questionable information or exaggerated advertisements. Moreover, many CHPs are now being imported officially and individually in today's borderless world. Voluntary management by manufacturers should have limitations. Finally, current consumer centers in Japan should allow consumers free access and inform them of what is correct and what is wrong with CHPs. All permitted information should be provided, regardless of whether there is evidence or not, pursuant to regulations for specialists at consumer centers. If consumer centers cannot fulfill this role, a center to provide comprehensive information on CHPs should be established. In addition to establishing an information provision system, consumers should be correctly informed of the categories of CHPs since 38.0% of pharmacists knew the categories of CHPs (data not shown). The newly established consumer affairs office should take the initiative in providing appropriate information on CHPs.

In the current study, only a domestic survey was performed. Of course, similar gaps in the information sharing with regard to CHPs are likely to exist in the United States. In the United States, however, foods are simply categorized as conventional foods and dietary supplements, so there are no such categories of CHPs as exist in Japan. Furthermore, forms of dietary supplements are restricted to pills, tablets, capsules, or liquids. Additionally, labels on dietary supplements are legally required (18). Thus, gaps in information sharing with regard to CHPs are assumed to be smaller in the United States than in Japan.

In the current study, the survey focused only on CHPs. There are, however, numerous complementary and alternative medicines (CAM) (19) to improve health. With a CAM, consumers and providers usually contact each other directly. Thus, gaps in information sharing with regard to CAM are assumed to be smaller

than those with regard to CHPs. The authors intend to focus on gaps in information sharing with regard to CAM in the near future.

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References

1. Formation of a good cycle of innovation and market. Council of Industrial Constitution, Ministry of Economy, Trade and Industry, 2001 Dec. <http://www.meti.go.jp/report/downloadfiles/g11212bj.pdf>.
2. Review of Institution of "Health Care Food". Food, Pharmaceutical and Medical Bureau, Ministry of Health, Labour and Welfare, 2005, Feb. <http://www.mhlw.go.jp/topics/bukyoku/iyaku/syoku-anzen/hokenkinou/seidominaosi.html>.
3. A Food Form of Food for Specified Health Use. Food, Pharmaceutical and Medical Bureau, Ministry of Health, Labour and Welfare, 2005, July. <http://www.mhlw.go.jp/topics/bukyoku/iyaku/syoku-anzen/hokenkinou/dl/06.pdf#search>.
4. Indication of Disease Risk Reduction of Food for Specified Health Use. Food, Pharmaceutical and Medical Bureau, Ministry of Health, Labour and Welfare, 2005, Feb. <http://www.nihs.go.jp/hse/food-info/mhlw/news/2005/050203/050203-12.pdf> (or <http://www.jhnfa.org/tokuhou34.pdf#search>).
5. Revision of Treatment of Food with Nutrient Function Claims Accompanying Review of Institution of "Health Care Food". Food, Pharmaceutical and Medical Bureau, Ministry of Health, Labour and Welfare, 2005, Feb. <http://www.nihs.go.jp/hse/food-info/mhlw/news/2005/050203/050203-7.pdf> (or <http://www.jhnfa.org/tokuhou32.pdf#search>).
6. Revision of Foundation of "Food for health use" Institution accompanying establishment of standard of Japanese food intake. Food, Pharmaceutical and Medical Bureau, Ministry of Health, Labour and Welfare, 2005, July. <http://www.nihs.go.jp/hse/food-info/mhlw/news/2005/050704/050704-0701002.pdf>.
7. Standard policy of reasonable manufacturing of food including tablet and capsule and Guideline of self-validation concerning safety of raw materials of tablet and capsule like food. Food, Pharmaceutical and Medical Bureau, Ministry of Health, Labour and Welfare, 2005, Feb. <http://www.nihs.go.jp/hse/food-info/mhlw/news/2005/050203/050203-9.pdf>.
8. Standard policy of training of advisory staff for food for

- health use and so on. Food, Pharmaceutical and Medical Bureau, Ministry of Health, Labour and Welfare, 2005, Feb. <http://www.mhlw.go.jp/topics/bukyoku/iyaku/syokusanzen/hokenkinou/1d-7.html>.
9. Hiromichi Kimura, Shintaro Sengoku. Companies approaching toward Food and Health in earnest. Kanki Publishing Ltd., Tokyo, Japan, 2006.
 10. Hamada K, Doi T, Sakura M, Matsumoto K, Yanagisawa K, Suzuki T, Kikuchi N, Okuda J, Miyazaki H, Okoshi H, Zeniya M, Asukata I. Effects of hydration on fluid balance and lower-extremity blood viscosity during long airplane flights. *JAMA*. 2002; 287:844-845.
 11. Information of harmful for health and Information of non-permitted medicines. Homepage of Ministry of Health, Labour and Welfare. <http://www-bm.mhlw.go.jp/kinkyu/diet.html>.
 12. Awareness of Food for Specified Health Use among general consumers. Mitsubishi Research Institute, Inc. 2005. <http://research.goo.ne.jp/database/data/000038/>.
 13. Awareness of Consumer Healthcare Products and action among house wives. National Consumer Affairs Center of Japan, 2005. http://www.kokusen.go.jp/news/data/n-20050304_2.html.
 14. Survey of usage of Consumer Healthcare Products. Mitsubishi Research Institute, Inc. 2006. <http://research.goo.ne.jp/database/data/000368/>.
 15. Hayashi Y, Kanda M, Fujii S, *et al*. Awareness of life-style related disease and situation of consumer healthcare products and supplements. *Kyouzai Iho*. 2005; 54:53-56.
 16. Ishihara J, Sobue T, Yamamoto S, Sasaki S, Tsugane S; JPHC Study Group. Demographics, lifestyles, health characteristics, and dietary intake among dietary supplement users in Japan. *Int J Epidemiol*. 2003; 32:546-553.
 17. Lyle BJ, Mares-Perlman JA, Klein BE, Klein R, Greger JL. Supplement users differ from nonusers in demographic, lifestyle, dietary and health characteristics. *J Nutr*. 1998; 128:2355-2362.
 18. Systems of Healthcare Products in America, Home page of Ministry of Health, Labour and Welfare. <http://www.mhlw.go.jp/shingi/2003/04/s0423-6b9.html>.
 19. National Center of Complementary and Alternative Medicine home page. <http://nccam.nih.gov/>.
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