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# Descriptive Study on the Circumstances concerning Confirmation of Contraindications and Careful Administration upon Purchasing Over-the-Counter Cold Medication and Manifestation of After-use Urinary Disorders

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Over-the-counter medications are primarily for self-medication, where the seller, such as a pharmacist, provides the necessary information and the consumer uses the medication at his or her own discretion based on the information provided. A Web survey was conducted from February 8 to 13, 2006, involving 500 men and women, ranging in age from 50 to 69 years, who had purchased over-the-counter medications for the common cold within the past 3 years. Upon consultation with and purchase of a cold medication from a pharmacist, 84.2% of respondents reported "being asked my symptoms," and less frequently (12.3–21.3%) being asked about contraindications/careful administration. Most respondents (60.8%) when asked whether they confirmed "contraindications/careful administration" responded negatively, stating they "occasionally do not confirm" or "do not confirm." In addition, among men aged 50–69 years, it became clear that 6.0% had experienced aggravation of prostatic hypertrophy symptoms after taking a cold medication. It is assumed that symptoms are usually confirmed upon the sale of over-the-counter medications, but the rate of confirming whether the consumer may need to consider contraindications/careful administration is low. Urinary retention is a preventable side effect because the confirmation prior to taking the medication can be made. Accordingly, some of those side effects can be avoided by ensuring the environment for confirming whether the individual corresponds to "contraindications/careful administration" before taking the medication.

**Key words**—over-the-counter medication; cold medication; contraindication; careful administration; urinary retention; Web survey

#### INTRODUCTION

The attitude of the public toward medication has been changing in recent years. The idea of self-medication has become common due to the increasing number of people keenly interested in their own health together with the fact that the proportion of the elderly in the general population has been increasing at an extremely rapid pace, as have diseases associated with adult lifestyle habits. The World Health Organization (WHO) defines self-medication as the selection of medication by individuals to treat selfrecognized illnesses or symptoms. Over-the-counter medications are sold primarily for self-medication, where the seller, such as a pharmacist, provides the necessary information and the consumer uses the medication at his or her own discretion based on the information provided. The methods for confirming proper usage when a consumer takes over-the-counter

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medications are "labeling on the outside of the box," "precautions for use," and "explanation on purchase."

Consumer awareness regarding over-the-counter medication in Japan, such as the concept of selfmedication which involves an understanding of active ingredients, effects, and efficacy, and the selection of a single-ingredient medication that is effective for a specific symptom, is not very high according to a market survey report conducted by the Japan External Trade Organization.<sup>1)</sup> This problem also stems from the public mostly taking medications prescribed by a physician under the universal healthcare system, in which drug information, including that on side effects, is not sufficiently provided on labeling. In addition, medications for the common cold, which are the most frequently purchased, are mostly complex preparations that are effective for multiple symptoms.<sup>1)</sup> The antipyretic analgesic drugs, antihistamines, and antitussives and expectorants are combined in "multicold medication," which is a

complex medication. Antihistamines are combined for the purpose of alleviating symptoms such as "runny and stuffy nose." Although the antihistamines are effective for acrinia of nasal secretion, because they have a degree of affinity to the muscarinic receptor structure, they are contraindicated for patients with lower obstructive uropathy such as prostatic hypertrophic patients, and glaucoma patients.<sup>2)</sup> Chlorpheniramine maleate and diphenhydramine hydrochloride included in medications for the common cold are also used in ethical drugs; however, package inserts state that they are contraindicated for patients with lower obstructive uropathy such as prostatic hypertrophy, and for patients with glaucoma. On the other hand, the package inserts for many over-the-counter medications mention that individuals with dysuria should consult with a physician/ pharmacist before taking them. According to a study of 195 specifications of nonprescription products by Kizu et al.,3) the contraindication information could not be accessed without opening the package for 87 specifications and 61 products.

Therefore, in this study, we investigated the actual situation of purchasing "medications for the common cold" primarily by examining "confirming the situation related to contraindications/careful administration" for consumers who had taking overthe-counter medications for the common cold. Specifically, prostatic hypertrophy is present in 44% of Japanese men in their 50s and in 52% of those in their 60s. The side effects of cold medications which are aggravated by prostatic hypertrophy are preventable side effects because confirmation prior to taking the medication can be made. In addition, we studied the conditions underlying manifestations of "symptoms of aggravated prostatic hypertrophy."

### **CONSUMERS AND METHODS**

The consumers participating in this study were selected from the contract monitors of NTT Visual Communication Co., Ltd. They comprised 500 men and women, ranging from 50 to 69 years of age (men and women in their 50s and 60s, 125 subjects, respectively) who had purchased over-the-counter medications for the common cold within the past 3 years.

**Survey Period** A Web survey was conducted from February 8 to 13, 2006.

**Establishment of Survey Items** This study was conducted with consumers who had purchased com-

mon cold medications at a pharmacy or drugstore within the past 3 years.

Consultation Experience with a Pharmacist and Reason for Choosing to Have a Consultation (Q1, **SQ1, Q2, and SQ2**) Consumers who had consulted with a pharmacist when purchasing their "cold medication" were questioned in detail regarding the content of the consultation. "Contraindications/ careful administration" were addressed in the questions, "Do you have any other health conditions?" and "What types of health conditions have you experienced?" Subsequently, preferences regarding consultation were surveyed using the three selections of "wanted to consult with a pharmacist," "wanted to consult with someone, but the person did not need to be a pharmacist," and "did not want to consult with anyone." Those consumers who did not respond that they "wanted to consult with a pharmacist" were then asked their reason for believing that it was not necessary for them to have a consultation.

Points of Attention and Confusing Issues when Selecting "Cold Medication" and Confirmation of Individuals Subject to "Contraindications/Careful Administration" (Q3, Q4, Q5, and SQ5) consumers were asked about what they paid attention to when selecting a cold medication. In this question, alternative responses including "trying to select a medication that is effective for my symptoms" and "trying to select a medication that is effective not only for my symptoms but also for other common cold symptoms as well (like the multicold medication)" were offered to understand the tendency to select multicold medications. Furthermore, the alternative response "based on the image and impression of the pharmaceutical manufacturer, brand, and advertisement (commercial)" was offered to determine the influence of the media on their choice. The next question addressed problems experienced upon purchasing the "cold medication" and centered on labeling on the box and package inserts, which are important sources of information for self-medication. In addition, a question addressing whether they had confirmed the situation related to "contraindications/ careful administration" was asked, and individuals who had not confirmed the situation were asked for the reason.

Trends in Visiting the Outpatient Clinic upon Implementation of the Proposed Medical Service System Reform (Q6) A question concerning the respon-

dent's intention of visiting the outpatient clinic to receive a JPY 1000 exemption from copayment liability was asked for the purpose of predicting the trend if the outpatient fixed-fee system comes into effect, as advocated in the Medical System Reform Implementation Proposal.

#### Occurrence of Side Effects (O7, O8, O9, and SO9)

To clarify the occurrence of side effects after taking a cold medication, survey questions focused on the aggravation of prostatic hypertrophic symptoms, especially those related to anticholinergic effects, which are the side effects of antihistamines including those contained in many common cold medications. These questions were asked only of men. Subjective symptoms of prostatic hypertrophy were initially explained and then it was asked whether the corresponding symptoms had occurred. The explanation of subjective symptoms was made with reference to the International Prostate Symptom Score (IPSS) for the assessment of severity of prostatic hypertrophy. Then, after being questioned on their understanding that the side effects may aggravate prostatic hypertrophy, the respondents were asked a question to address their personal experience of prostatic hypertrophic aggravation after taking the cold medication, choosing from "experienced aggravation," "experienced new symptom manifestation," "experienced being unable to urinate," "experienced no such symptoms," and "cannot remember." The types of medication being used when the symptoms manifested were also verified.

Statistical Analysis All results are described in terms of descriptive statistical values.

#### RESULTS

**Respondent Characteristics** The characteristics of respondents are shown in Table 1. The age and sex ratio was 1:1, and respondents resided in Tokyo (36.4%), Kanagawa (28.6%), Saitama (16.4%), and Chiba (18.6%). The occupational breakdown showed that many men were involved in self-owned businesses, while most women were housewives.

## Consultation Experience with a Pharmacist and Reason for Choosing a Consultation when Purchasing a Cold Medication (Q1, SQ1, Q2, and SQ2)

The results regarding the consultation experience with a pharmacist and the items asked by the pharmacist during consultation are shown in Table 2: "respondents who had a consultation" comprised 44.4%; "respondents who had a consultation, but did not know whether it was with a pharmacist" comprised 17.6%; and "respondents who had no consul-

| Age  | Total |      | Men |      | Women |     |
|--|-------|------|-----|------|-------|-----|
|  | n     | %    | n   | %    | n     | %   |
| 50∼59 years                                      | 250   | 50.0 | 125 | 50.0 | 125   | 50. |
| 60∼69 years                                      | 250   | 50.0 | 125 | 50.0 | 125   | 50. |
| total  | 500   | 100  | 250 | 100  | 250   | 100 |
| Occupation                                       | n     | %    | n   | %    | n     | %   |
| Office worker/sales worker                       | 39    | 7.8  | 27  | 10.8 | 12    | 4.  |
| Engineer/specialist                              | 32    | 6.4  | 28  | 11.2 | 4     | 1.  |
| Sales/service worker                             | 22    | 4.4  | 20  | 8.0  | 2     | 0.  |
| Aministrator                                     | 21    | 4.2  | 19  | 7.6  | 2     | 0.  |
| Company officer/proprietor                       | 26    | 5.2  | 25  | 10.0 | 1     | 0.  |
| Lawyer, accountant, etc.                         | 2     | 0.4  | 2   | 0.8  | 0     | 0.  |
| Self-employed                                    | 70    | 14.0 | 54  | 21.6 | 16    | 6.  |
| Working wife (includes part-time/temporary work) | 43    | 8.6  | 0   | 0.0  | 43    | 17. |
| Housewife  | 146   | 29.2 | 0   | 0.0  | 146   | 58. |
| Student  | 0     | 0.0  | 0   | 0.0  | 0     | 0.  |
| Unemployed                                       | 76    | 15.2 | 56  | 22.4 | 20    | 8.  |
| None of the above are applicable                 | 23    | 4.6  | 19  | 7.6  | 4     | 1.  |
| total  | 500   | 100  | 250 | 100  | 250   | 100 |

Pagnandant Characteristics

Table 2. Consultation Experience with a Pharmacist upon Purchasing a "Cold Medicication" and the Items Questioned by the Pharmacist at the Time of Consultation

| Q1 When you purchased the "cold medication" did you consult with or ask advice from a pharmacist in the pharmacy or drugstore? | n   | %    |
|--|-----|------|
| I have had a consultation  | 222 | 44.4 |
| I have had a consultation, but the pharmacist did not know about it  | 88  | 17.6 |
| I have not had a consultation  | 190 | 38.0 |
| Total  | 500 | 100  |
| SQ 1 When you had the consultation, what kind of things were you asked about by the pharmacist? (Multiple responses allowed.)  | n   | %    |
| What kind of symptoms do you have  | 261 | 84.2 |
| Have you experienced any allergies or side effects when taking a medication  | 156 | 50.3 |
| Are you taking any other medications   | 127 | 41.0 |
| Do you suffer from any other health conditions   | 66  | 21.3 |
| Do you have food allergies   | 59  | 19.0 |
| The person in the store answered my question without asking me anything  | 56  | 18.1 |
| Do you have a health problem that you have been suffering from, up until now   | 38  | 12.3 |
| Are you pregnant/breast feeding  | 8   | 2.6  |
| I cannot remember  | 0   | 0.0  |
| None of the above is applicable  | 1   | 0.3  |
| Total  | 310 |      |

Table 3. Desire to Have a Consultation with a Pharmacist at the Time of Purchasing a "Cold Mediccation"

| Q2 When you are purchasing a "cold medication" in the pharmacy or drugstore, do you think of wanting to consult with a pharmacist or another related individual in the store in order to buy it? | n   | %    |
|--|-----|------|
| I would like to consult with a pharmacist, if possible   | 294 | 58.8 |
| When I purchase something I would like to consult with someone, but it is not necessary for me to consult with a pharmacist  | 82  | 16.4 |
| I do not want to consult with anyone in particular   | 124 | 24.8 |
| Total  | 500 | 100  |
| SQ2 What is the reason for thinking that you don't need to consult with a pharmacist in the pharmacy? (Multiple responses allowed.)  | n   | %    |
| It is not necessary to have a consultation all of the time, when I take the same medication  | 81  | 39.3 |
| I think that over-the-counter medications should be safe   | 62  | 30.1 |
| Because I can generally understand by looking at the package label on the box  | 61  | 29.6 |
| Even if I had a consultation, they would probably be recommended medications that benefit the interests of the store   | 53  | 25.7 |
| Because I make a purchase after studying on my own   | 51  | 24.8 |
| I believe that most of the pharmacists are inadequate to consult with  | 28  | 13.6 |
| I haven't gotten an appropriate response when I have asked for advice in the past  | 23  | 11.2 |
| Because, I have nothing in particular to ask advice about  | 9   | 4.4  |
| None of the above is applicable  | 15  | 7.3  |
| Total  | 206 |      |

tation" comprised 38%. The items most frequently addressed by a pharmacist upon consultation and purchase of a cold medication was "being asked my symptoms" (84.2%), and less frequently "being asked whether I had another health condition" (21.3%) and "being asked the health condition (s)

that I had suffered up to that time" (12.3%).

The results after "choosing to have a consultation with a pharmacist" when purchasing a cold medication are shown in Table 3. The percentage of subjects who wanted to consult with a pharmacist when purchasing a medication for the common cold was

58.8%, who responded that they "wanted to consult with a pharmacist if possible." Moreover, the reason why individuals believed it was not necessary to consult with a pharmacist was asked of those who answered "when I purchase something I would like to consult with someone, but it is not necessary for me to consult with a pharmacist" or "I do not want to consult with anyone in particular." The most common response (39.3%) was "I always take the same medication, so I don't need a consultation," followed by (30.1%) "I think that over-the-counter medications should be safe."

Points of Attention and Confusing Issues when Selecting "Cold Medication" and Confirmation of Individuals Subject to "Contraindications/Careful Administration" (Q3, Q4, and Q5) The responses on the points paid attention to by consumers upon selecting a cold medication were, in order of frequency, "trying to select a medication that is effective for my symptoms" (54.6%), followed by "how to take a medication" (40.0%), and "trying to select a medication that is effective not only for my symptoms, but also for other common cold symptoms as

well" (36.4%) (Table 4). Responses for the problems consumers experienced upon selecting a "cold medication" were "it is difficult to know the difference between one product and another" (49.4%), and "the cautionary statement cannot be read in detail without opening the package" (34.2%) (Table 4). The response to the question on whether the consumer confirmed "contraindications/careful administration" was the sum of those responding "occasionally do not confirm" and "do not confirm" (60.8%) (Table 5).

# Trends in Visiting the Outpatient Clinic Based on Proposed Medical Service System Reform (Q6)

Regarding the trend in visiting the outpatient clinic after the proposed medical service system reform, 33.4% of respondents stated that "it won't be any different than it is now," 52.6% that "I suppose that trying treatment with over-the-counter medications might increase compared with the present," and 14.0% that "I have no idea" (data not shown).

Occurrence of Side Effects (Q7, Q8, Q9, and SQ9), Circumstances Surrounding the Recognition of Side Effects and the Experience of Side Effect Manifesta-

Table 4. Points of Attention and Confusing Issues when Selecting a "Cold Medicatione"

| Q3 When you select a cold medication, what kind of things do you pay careful attention to? (Multiple responses allowed.)                           |     |      |
|--|-----|------|
| I try to select a medication that is just effective for my own symptoms  | 273 | 54.6 |
| How to take the medication, such as how many times a day, how many tablets at a time, and when it should be taken                                  | 200 | 40.0 |
| I try to select a medication that is effective not just for the symptoms I have now, but which is also good for other common cold symptoms as well | 182 | 36.4 |
| Price  | 155 | 31.0 |
| What kind of side effects it has   | 153 | 30.6 |
| If there is any drug interaction with other medications being taken  | 137 | 27.4 |
| What kind of things I should be careful about when taking the medication   | 135 | 27.0 |
| According to the pharmaceutical manufacturer, brand, and the image and or the impression of the advertisement                                      | 91  | 18.2 |
| Whether I correspond to someone who should not take the drug, or not   | 90  | 18.0 |
| None of the above is applicable  | 10  | 2.0  |
| Total  | 500 |      |
| Q4 Do you have any problems in selecting a cold medication? (Multiple responses allowed.)  | n   | %    |
| It is difficult to know the difference between one product and another   | 247 | 49.4 |
| I cannot read the cautionary statement in detail without opening the package   | 171 | 34.2 |
| The characters on the package are too small  | 142 | 28.4 |
| I am not having any problem with it, in particular   | 109 | 21.8 |
| I can't tell from the package information, whether I correspond to someone who should not take the drug, or not                                    | 105 | 21.0 |
| The description on a package is hard to understand   | 94  | 18.8 |
| Although I want to select a single ingredient product, there are only multi-ingredient products available  | 51  | 10.2 |
| Among these, none of the above is applicable   | 15  | 3.0  |
| Total  | 500 |      |

Table 5. The Proportion of Respondents Who Confirmed the Information about "Contraindication/Careful Administration"

| Q5 Precautions for "the individual who should not take the medication" AND "the individual who should consult with a physician/pharmacist before taking the medication" are described in the" cold medication" information. Are you making sure that you don't correspond to these individuals? Do you want to consult with a pharmacist or another related individual in the store in order to buy it? |     | %    |
|---|-----|------|
| I certainly make sure   | 196 | 39.2 |
| Occasionally I do not confirm   | 189 | 37.8 |
| I do not make sure  | 115 | 23.0 |
| Total   | 500 | 100  |
| SQ5 Please let us know why you do not make sure of the precautions for "individuals who should not take the medication" and "the individuals who should consult with a physician/pharmacist before taking the medication". (Multiple responses allowed.)  | n   | %    |
| I haven't had any problem in particular with taking the medication, to date   | 180 | 59.2 |
| I think I do not correspond with these individuals because I haven't had any particular health problem  | 118 | 38.8 |
| I take the same cold medication and it's good for me  | 99  | 32.6 |
| I had thought that there wasn't a big problem with my using it because it's a over-the-counter medication   | 56  | 18.4 |
| There is no detailed description on the package box   |     | 13.2 |
| I did not know there is a cold medication that some people shouldn't take   |     | 8.6  |
| I do not confirm by myself because I consult with a pharmacist  |     | 6.6  |
| None of the above is applicable   | 16  | 5.3  |
| Total   | 304 |      |

tion Regarding the item asking whether the individual had a symptom suggesting prostatic hypertrophy, 10.8% of the 250 men respondents answered that "I have been diagnosed or am currently being diagnosed with it," and 37.6% answered that "I have a suspicious symptom." Thus, fewer than 50% of the respondents may have suspected prostatic hypertrophy (data not shown). Furthermore, when asked about the awareness of side effects, such as the potential for aggravation of "prostatic hypertrophy" with over-the-counter cold medications, 3.2% of respondents stated that "I am aware of the details," 21.2% that "I have heard of it," and 75.6% that "I don't know anything about it at all" (data not shown). Among individuals who had experienced side effects, 70.2% responded "I did not know at all" about the side effects, including the aggravation of prostatic hypertrophy (Table 6). Furthermore, according to the results of questions on the occurrence of prostatic hypertrophic aggravation upon taking a cold medication, 6.0% responded that they had "experienced aggravation," "experienced new symptom manifestation," or "experienced being unable to urinate." Those who had experienced urinary retention comprised 3.6%. Moreover, 46.7% responded they had experienced urinary retention and answered the question, "Which type of cold medication caused such side effects?" with a "multicold medication."

#### DISCUSSION

According to the results of this study, although pharmacists or other pharmacy staff were asked about symptoms 84.2% of the time during consultation, only 21.3% of respondents had been asked, "Do you have any other health conditions?", which corresponds with verifying the "contraindications/careful administration," and 12.3% had been asked, "Have you had other health condition?" According to the report by Shiragami,<sup>5)</sup> the rate of response by pharmacists regarding their explanation of effects and efficacy was 67.5%; whereas the response by pharmacists regarding their explanation of "cautions about age and health conditions" for contraindications/careful administration was 30.9%. Therefore, it is assumed that symptoms are often confirmed upon the sale of over-the-counter medications, but the rate of confirming whether the consumer is relevant to the contraindications/careful administration is low.

In addition, in men aged 50–69 years, in this study 6.0% had experienced aggravation of prostatic hypertrophy symptoms and 3.6% had experienced urinary retention after taking a common cold medication. Oshima *et al.* reported that 6.6% of individuals were in the "contraindication/careful administration" category in their background study of 257 users of over-the-counter medication, of a very similar percen-

Table 6. Circumstances Surrounding the Understanding of Side Effects, and Experience of the Appearance of Symptoms of "Prostatic Hypertrophic Aggravation" upon Taking a Cold Medication

| Q8 Do you know that over-the-counter cold medication has side effects such as "prostatic hypertrophical aggravation"?   | n   | %    |
|---|-----|------|
| I know it in detail   | 8   | 3.2  |
| I have heard of it  | 53  | 21.2 |
| I did not know at all   | 189 | 75.6 |
| Total   | 250 | 100  |
| Q9 As a result of taking a cold medication, have you experienced newly manifesting symptoms which are suspicious of "prostatic hypertrophy" or the aggravation of "prostatic hypertrophy" up until now? | n   | %    |
| I have experienced aggravation  | 2   | 0.8  |
| I have experienced the appearance of a new symptom  | 4   | 1.6  |
| I have experienced being unable to urinate  | 9   | 3.6  |
| I have never experienced such symptoms  | 175 | 70.0 |
| I cannot remember   | 60  | 24.0 |
| Total   | 250 | 100  |
| SQ9 What kind of cold medication is the drug that caused such an incident?  | n   | %    |
| Multicold medication  | 7   | 46.7 |
| Other type of "cold medication"   | 2   | 13.3 |
| I cannot remember   | 6   | 40.0 |
| Total   | 15  | 100  |

tage to those respondents who reported experiencing prostatic hypertrophy aggravation in the present study. An increase in the size of the inner prostate gland occurs with aging in men over 50, and some develop clinical manifestations. In Japanese men, prostatic hypertrophy occurs in 44% in their 50s, 52 % in their 60s, and 63% in their 70s.<sup>4)</sup> Of the 250 men in this study, 48.4% reported that they had been diagnosed with or had suspicious symptoms of prostatic hypertrophy, and approximately half of the men aged 50 to 69 years had or were suspected to have prostatic hypertrophy. Among the 250 men, 75.6% responded that they did not know about the side effects, such as prostatic hypertrophic aggravation due to combination cold medications. The side effects of cold medications that aggravate prostatic hypertrophy symptoms are preventable, if confirmation prior to taking the medication can be made. Accordingly, it is necessary to determine whether an individual corresponds to the "contraindications/careful administration" before selling the medication.

This study found that 34.2% of respondents in response to Q4, "Do you have problems in selecting a cold medication?" answered that "I cannot read the cautionary statement in detail without opening the package," and 21% responded that "I cannot tell

whether I correspond to: 'an individual who should not take the medication' or 'an individual who should consult with a physician/pharmacist prior to taking the medication' from the labeling on the box." According to the study by Kizu et al.,3) of 195 specifications of nonprescription products, the contraindication information could not be accessed without opening the package for 87 specifications and 61 products. Otsuka et al. pointed out that the safety information in Japan is insufficient compared to that in the USA.<sup>7,8)</sup> It appears necessary to increase the safety information on the package so that the risks can be understood at the purchasing stage. This would be beneficial since 13.2% of our respondents who did not read contraindications/careful administration said one reason was that "there was no detailed description on the package."

When 15 persons who had experienced prostatic hypertrophic aggravation were which type of medication had been taken, 46.7% answered that it was a multicold medication, 13.3% that it was another type, and 40% could not remember. Most over-the-counter cold medications are complex and effective for various symptoms. In addition, most products are combined with antihistamines, and there are few choices available for self-medication without taking

an antihistamine. Two-hundred and ninety-nine multicold medications are in the Self-Medication Data-Base of the Japan Self-Medication Industry. 9) Among them, antihistamines are contained in about 75%. According to a study of consumer advisors conducted by the Japan External Trade Organization, more than 60% of individuals responded that they "did not know" how to recognize complex and single-ingredient medications.<sup>1)</sup> In addition, upon questioning whether one would select complex or single-ingredient medications after an introduction to the differences between them and because almost all products for self-medication are complex medications, the majority responded with "it is better to select a single-ingredient medication that is effective for a specific symptom," only 16% responded that "it is better to take complex medications, because selecting medications is troublesome." In particular, among only those individuals who could not recognize single-ingredient medications, "the use of both single-ingredient medications and complex medications" was 50%, and "the use of the single-ingredient medications in a positive manner" was 30%. As a result of the responses given, encouraging single-ingredient medication sales appears to be necessary.

According to our results, in "confirming contraindications / careful administration," which responds to "precautions," although 39.2% of respondents said that they confirmed the contraindications/careful administration information, only 18.0% said that they would confirm whether not it was appropriate for them to take a cold medication. Usami et al. reported that 17% of their respondents read about "matters one should not do." Even in the present study, among the 206 subjects who responded "occasionally do not confirm" and "do not confirm" for Q5, the reason for not confirming the precaution was "I haven't had any problem in particular with taking the drug, to date" (59.2%), and "I think I do not correspond to these individuals because I haven't had any particular health problem" (38.8%). However, 6 individuals had been diagnosed with prostatic hypertrophy, and 24 of the 59 men believed that they did not have a chronic health condition with suspicious symptoms of prostatic hypertrophy, although they had not been diagnosed as such. In a study in asthmatic patients by Watanabe et al., it was reported that approximately 70% of patients had not been told about their asthma as an issue of caution when they sought diagnosis and purchased medications, and only half recognized the possibility that antipyretic analgesic drugs, such as aspirin, could induce asthma.<sup>11)</sup> Consumer education is considered necessary to select appropriate drugs because 60% of individuals are reported to stock multiple cold medication in the household.<sup>5)</sup>

For the question in this study regarding whether respondents wanted to consult a pharmacist when purchasing a cold medication, 58.8% responded that they would like to do so if possible. Of note, 11 of the 15 who had experienced prostatic hypertrophic aggravation responded positively. The reason for not consulting a pharmacist was given by 39.3% as "It is not necessary to have a consultation all of the time when I take the same medication," by 30.1% as "I think that over-the-counter medications should be safe," and by 29.6% as "I can generally understand by looking at the package label." Further, 13.6% of respondents believed that "most pharmacists are inadequate for consultation." However, the possibility has been pointed out that pharmacists in Japan do not fulfill their occupational function as specialists in the sale of over-the-counter medications. Sugawara et al. calculated the effect of switching to over-the-counter medication on medical care expenses using conjoint analysis, and found that there would be a 13% decrease in such expenses without an in-depth explanation by a pharmacist and a 34.5% decrease with an in-depth explanation.<sup>12)</sup> Scar et al. reported that 7.1% of problems were also preventable by employing the assistance of a final-year pharmacy school student as a seller for over-the-counter medications.<sup>13)</sup> Active participation should be expected from medication specialists.

This study involved a population of research company monitors in their 50s and 60s. Although there was a bias because all were company monitors, it is thought that this dose not significantly alter the results because it can be assumed that the prevalence of prostatic hypertrophy in the general population is greater than among the participants in this study due to the increasing number of senior citizens in Japanese society. Also, even though all were metropolitan area residents and the study involved a survey method conducted on the Internet, according to the Internet White Paper 2006, it is reported that the Internet penetration rate for households (the percentage of households in which there is an Internet user

regardless of the location of use and connection apparatus) was  $85.4\%^{14)}$  in Japan. Thus our results should still be representative of the general population.

The International Pharmaceutical Federation has published guidelines to clarify the role of the pharmacist, company, and physician in creating an environment for responsible self-medication, in which the importance of cooperation by all of the professionals surrounding consumers is mentioned. In the present study, 52.6% of respondents stated that self-medication opportunities would increase if the proposed reform of the medical-care system occurred. Therefore, in addition to the fact that pharmacists should become involved in a proactive way, it is necessary for consumers themselves to contribute to an environment conducive to determining the proper usage of over-the-counter drugs.

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