《 Original Article 》

The degrees of influences on identification via information on the short-sides of a pharmaceutical packaging box

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The purpose of this study, performing experiments and surveys, was to clarify the influences on identification by short-side information of rectangular pharmaceutical packaging boxes, from the viewpoint of preventing pharmacists from dispensing errors such as mixing up medications. In experiments, research participants were shown sample sheets where designs were placed on the short-side surface of pharmaceutical packaging boxes. Participants were assigned to identify designated pharmaceutical products within a given time. In questionnaire surveys, they were queried regarding four types of "designs on the short sides of rectangular packages" and six types of "designs for specifications". The results confirmed that for the distinctiveness of "short side designs", the design type with different design patterns based on each product and different colors based on each specification was effective for identification. Furthermore, this survey clarified that a "specification design" with distinctiveness for identification was the design type where each specification was assigned different colors and other specifications were inscribed. It was suggested that color-related distinction for short-side designs was effective for identifying the same products. For specification designs, however, a design which enabled pharmacists to perceive which products had multiple strength types in the specifications was necessary to prevent dispensing errors of picking the wrong dose specifications.

Key words; pharmaceutical packaging box, short side, design, color, multiple specifications

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1. Introduction

Currently, pharmaceutical products stored in health insurance pharmacies have increased in number, along with promoted use of generic pharmaceutical products and due to changes of

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calculation requirements in the medical dispensing fee revisions [1-5]. According to the survey conducted in 2015 by Japan Pharmaceutical Association [6], the average number of medicines in the medicine inventory was 1,053.9 types in 818 health insurance pharmacies, as answered in the questionnaire survey. Among the pharmaceutical products, the generic products averaged at 278.9. Stock quantities of 1,000 or more types account for 47.4%, almost half, of the total from pharmacies, 700 to 1,000 accounted for 39.6%, and fewer than 700 account for 13.0%. In this circumstance of increased stockpiles, storage spaces are limited and medical products are placed on shelves above the dispensing cabinet and stored in drawers of the cabinet. PTP (press through package) sheets of most drugs remain in their individual boxes. When preparing in most pharmacies, pharmacists identify medicines depending on product information on the short-sides of package boxes. Our previous research, which was conducted with an aim to prevent pharmacists from dispensing errors, reported that when a label design on the short-side uses the same color on the front side, it was effective to distinguish product items [7]. The Incident Collection and Analysis Project of "Hiyari-hatto", close call, in Pharmacy [8] reported that a large number of dispensing errors occurred via picking up the wrong content type from specifications. For items with multiple specifications, particularly, effective label designs are necessary to help distinguish products. Therefore, we aimed to clarify how design pattern, color, and layout of the package short-sides influence identification for pharmacists, examining distinguishable product information on packaging boxes from the viewpoint of preventing pharmacists from dispensing errors.

2. Methods

1. Subjects and research methods

Identification experiments: Subjects were 90 pharmacists who participated in a seminar of Shonan Higashi Area Pharmaceutical Association, which was held in Kanagawa Prefecture in March 2019.

Questionnaire surveys: Subjects were 406 pharmacists who participated in seminars held in Yamaguchi Prefecture in May–July 2019 by Ube Pharmaceutical Association, Shuyaku-kai Association Academic Lecture, Shimonoseki City Pharmaceutical Association, Hofu Pharmaceutical Association, Yamaguchi City Pharmaceutical Association, Yamaguchi Society of Hospital Pharmacists Pharmaceutical Research Seminar and Hagi Pharmaceutical Association.

These seminars, in which our surveys were performed, were held for pharmacists without entry restrictions on occupational category, age and experience.

2. Identification experiments

Subjects moved to a position where they were able to adequately distinguish images displayed on the screen and watched four types of sample sheets in order. The sample sheets simulated a drawer of a dispensing cabinet, where designs on the short-sides of rectangular packaging boxes were arranged. Sample sheet I: Same design pattern and same color (Fig. 1-a). Sample sheet II: Different design patterns for each article and same color (Fig. 1-b). Sample sheet III: Same design pattern and different colors for each article (Fig. 1-c). Sample sheet IV: Different design patterns and different colors for

a) Sample sheet I

b) Sample sheet II

c) Sample sheet III

d) Sample sheet IV

Fig. 1 Sample sheets of the designs on short-sides of individual package boxes used in the identification experiments

a) Sample sheet I: Same design pattern and same color
b) Sample sheet II: Different design pattern for each article
c) Sample sheet III: Different colors for each article
d) Sample sheet IV: Different designs and different colors for each article

each article (Fig. 1-d). Subjects were assigned to identify a designated item on each sheet within the given time, ten seconds; they were shown the sample sheets in order. After the experiments, we counted the number of subjects in a manner of raising a hand, when they identified the designated items. Based on the experimental results, we compared the four ratios of the number of subjects who identified the item for each sample sheet.

The sample sheets were created as follows: As for pharmaceutical agents which begin with "ア", "*a*", 21 articles (63 items) were selected based on usage frequency in pharmacies in descending order. On a sheet which represented a storage drawer, 1 – 63 location numbers were allocated. Random numbers were generated for 63 agent item cells employing the RANDBTWEEN function. Randomized numbers were applied from "1" in ascending order and then, duplicated numbers were randomized using random numbers which were not overlapped. After consulting TOYAMA SUGAKI Co., Ltd. regarding designs on the short-sides of packaging

Design A　　Design B

Design C　　Design D

Fig. 2　Sample sheets on the short-sides of package boxes used in the questionnaire survey

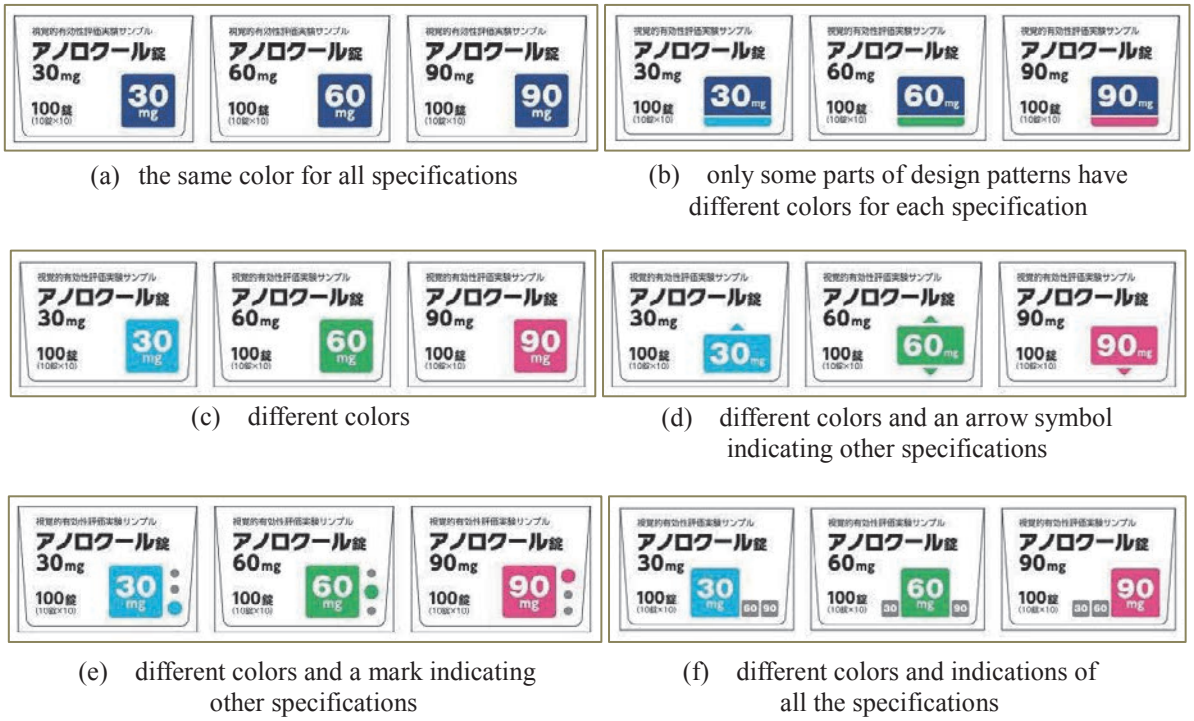
boxes, font type, position and size were decided in accordance with widely used standard designs. The given time, ten seconds, were from showing to hiding a sample sheet in each experiment.

3. Questionnaire surveys

3.1 Identification of designs on the short-sides of pharmaceutical package boxes

For the questionnaire survey, four different types of product designs were employed. The design rule was as follows (Fig. 2). Design A: Design pattern is the same for all articles and colors are different for each content specification. Design B: Colors are different for each article and colors are different for each content specification. Design C: Design patterns are different for each article, and specifications have different colors for each specification but have a common design. Design D: Design patterns are different for each article and different colors for each content specification but with a common design pattern. In the survey, subjects were asked to rank the four sample sheets which had different design layouts, in terms of identification discriminability, and to answer their reasons regarding the first and fourth ranking.

The designs on the short-sides of packages in the sample sheets were created in the same manner of the identification experiments.



(a) the same color for all specifications

(b) only some parts of design patterns have different colors for each specification

(c) different colors

(d) different colors and an arrow symbol indicating other specifications

(e) different colors and a mark indicating other specifications

(f) different colors and indications of all the specifications

Fig. 3 Sample sheets of specification designs on the short-sides of packages used in questionnaire survey

3.2 Identification of specification designs on the short-sides of pharmaceutical package boxes

Six types of specification designs were created for the short-sides of boxes, in which tablets were supposed to be packed individually. The design rules were as follows (Fig. 3). (a): All specifications were shown in the same color. (b): Only some parts of the design patterns have different colors for each specification. (c): Colors are different for each specification. (d): Each specification has different colors and an arrow symbol which means that the product is a type with multiple drug concentrations, having other specifications. (e): Each specification has a different color and a mark which means that the drug has other specifications. (f): Each specification has different colors and indicates all the specifications that the product has. The participants were asked to rank the six designs for distinguishing products easily; six product types had different design layouts for the short-sides of packages. The subjects were asked for their reasons for the first and the sixth ranking. Furthermore, they assessed the necessity of the indication for multiple specifications, using an assessment scale with four steps; necessary, somewhat necessary, somewhat unnecessary, and unnecessary.

Package designs on the short-sides for sample sheets were created in the same manner of identification as the experiments.

4. Statistical analysis

The manner in which to calculate the scores in the survey regarding the identification for design on the short-sides of packages was as follows: four points were given to the first position, similarly, three points to the second, two points to the third and one

point to the fourth. The total scores were obtained. A box-and-whisker plot was created showing the quartile range from the median. Multi-analysis was performed using the Bonferroni approach. A significant level was $p<0.05/6=0.0083$. Furthermore, identification for specification of the box short-sides was assessed. Similarly, six points were given to the first position, five points to the second position, four points to the third position, three points to the fourth position, two points to the fifth position and one point to the sixth position. The points were calculated for the total scores. A box-and-whisker plot was created showing quartile range from the median. Multi-analysis was performed using the Bonferroni approach. A significant level was $p<0.05/15=0.0033$. The IBM SPSS Statistics version23 was employed for a statistical analysis.

5. Ethical considerations

Research participants in this study were fully informed about the meaning and contents of this research. Participations relied on the concept of individual autonomy. Furthermore, they were appropriately informed that confidentiality pertaining to participants and institutions was secure, and that they would not receive any disadvantage if they did not participate in the research, and the obtained information was not utilized for any other aims than this research. Participations in this experiment and replies to the questionnaires were considered to be the consent on research cooperation. This questionnaire survey was implemented with the Ethical Guidelines for Medical and Health Research Involving Human Subjects and conducted under an approval of the Ethics Review Committee on Research of general corporate judicial person, Yamaguchi Pharmaceutical Association (permission number 19-01).

3. Results

1. Identification experiments

The ratios of the number of subjects who identified the designated products in the experiments are shown in Table 1. The highest ratio was in sample sheet Ⅲ, whose design was the same design and different colors for each article.

2. Questionnaire surveys

The collection rate of this questionnaire survey was 100 percent.

Table 1　The ratios of subjects who identified the designated products in Sample sheets I–IV

	The number of subjects who identified the products (n=90)	The ratio of subjects who identified the products
Sample sheet I	26	28.9%
Sample sheet II	33	36.7%
Sample sheet III	43	47.8%
Sample sheet IV	34	37.8%

2.1 Identification of designs on the short-sides of pharmaceutical package boxes

The ranking positions in four designs were converted into scores by calculation for total scores based on the given points and subsequently, comparisons of the median values among Design A, B, C, and D were shown (Fig. 4). As a result, Design C was significantly high in median values in comparison with the other three designs.

The subjects gave their reasons for their first ranking. For <Design A>, the main reasons of their choices were “simple and conspicuous (n=9)”, and “specification is easily recognized (n=5)”. Similarly, the main reasons for <Design B> were “conspicuous (n=42)” and “subjects were able to recognize the same article (n=27)”. <Design C> were “conspicuous (n=65)” and “subjects were able to recognize that products were classified by each item and each specification (n=54)”. <Design D> were “it was good to have a common design (n=9)” and “articles and specifications were easily recognized (n=7)”.

The subjects gave their reasons for their fourth ranking. For <Design A>, the main reasons of their choices were “indistinct/hard to distinguish (n=115)” and “a risk of picking-up errors (n=34)”. Similarly, the main reasons for <Design B> were “as articles have the same color, specifications seemed to be easily mistaken (n=12)” and “As the color of the right and left bands is the same, specifications seemed to be easily mistaken (n=7)”. <Design C> were “indistinct/hard to distinguish (n=15)” and “information quantity is large (n=4)”. <Design D> were “as there are common designs, specification seems to be easily mistaken (n=23)” and “information quantity is large (n=7)”.

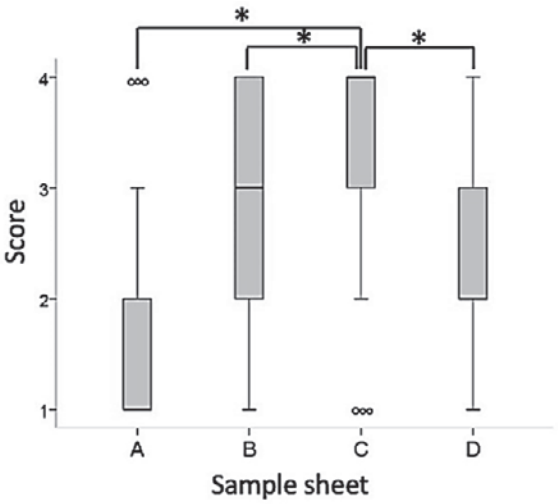


Fig. 4 Comparison in identifications among the four design types on the short sides of packages

Ranking positions for Design A, B, C, and D of the questionnaire responses were decided by calculating the total scores; four points were given to the first position, three points to the second, two points to the third and one point to the fourth. Aggregating data of questionnaire responses, four types of designs, A, B, C, and D, were examined where points 1–4 for the number of subjects were written for each design. With the purpose of detecting which point was the highest among 1–4 points, median values were calculated. A box-and-whisker plot was created showing the quartile range from the median. The box-and-whisker plot shows that the median is indicated with a horizontal line in the interior of a box, the bottom line of the box represents the first quartile (25%), the top line of the box represents the third quartile (25%). Both ends of the whiskers represent the maximum and the minimum values located within the 1.5 times length of the box. A white circle (○) outside the whisker was an outlier. A multi-analysis was performed using the Bonferroni approach. The significant level was $p<0.05/6=0.0083$. The marks of ＊ shown in Fig. 4 represent comparisons which were judged to have significant differences.

2.2 Identification of specification designs on the short-sides of pharmaceutical package boxes

Comparisons of the calculated total scores among all ranking positions were shown in (Fig. 5). The median value of design (f) was significantly high in comparisons with other designs.

The subjects gave their reasons for their first ranking. For (a), the main reasons of their choices were “simple and conspicuous (n=2)”, and “it is better not to have specific images (n=1)”. Similarly, (b): “conspicuous (n=7)”. (c): “simple and conspicuous (n=40)” and “specification designs catch attentions (n=8)”. (d): “all specifications are recognized/it is able to notice that the article has other specifications (n=12)” and “simple mark of arrows is a good design (n=5)”. (e): “all specifications are recognized/it helps to notice that the article has other specifications (n=52)” and “conspicuous (n=23)”. (f): “all specifications are recognized and it helps to notice that the article has other specifications (n=150)” and “conspicuous (n=25)”.

The subjects gave their reasons for their sixth ranking. For (a), the main reasons of their choices were “a risk of picking-up errors due to the same color (n=249)” and “There would be a large number of picking up wrong specifications (n=41)”. (b): “colors are not conspicuous (n=6)” and “figures look small due to color classification (n=1)”. (c): no answer. (d): “marks are confusing (n=2)”. (e): “marks are confusing (n=1)”, (f): “no need for indication of other specifications (n=3)” and “jumble (n=1)”.

The subjects answered a question on whether or not indication for other speculations is necessary, using an assessment scale with four steps. The survey results were “necessary (n=205: 50%)”, “somewhat necessary (n=155: 38%)”, “somewhat unnecessary (n=26: 6%)”, “unnecessary (n=9: 2%) and “blank (n=11: 3%)”.

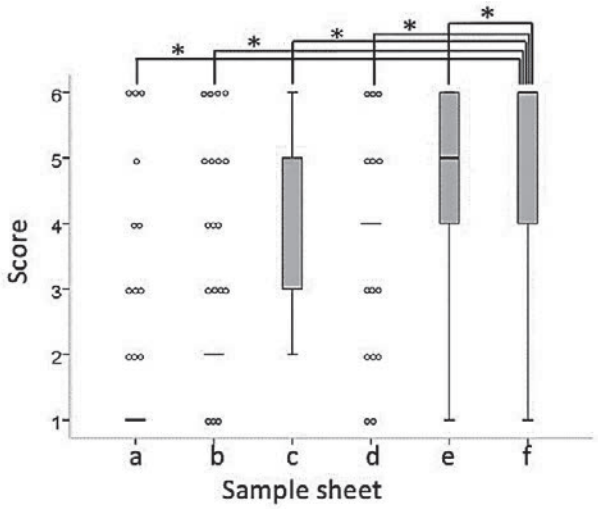


Fig. 5 Comparison in identifications among six design types on the short-sides of packages

The ranking positions for (a)–(f) in the questionnaire responses were decided by calculating the total scores; six points were given to the first position, five points to the second position, four points to the third position, three points to the fourth position, two points to the fifth position and one point to the sixth position. Aggregating data of the questionnaire responses, six types of designs were examined where points 1–6 for the number of subjects were written for each design. With the purpose of detecting which point was the highest among 1–6 points, median values were calculated. A box-and-whisker plot was created showing the quartile range from the median. The box-and-whisker plot shows that the median is indicated with a horizontal line in the interior of a box, the bottom line of the box represents the first quartile (25%), the top line of the box represents the third quartile (25%). Both ends of the whiskers represent the maximum and the minimum values located within the1.5 times length of the box. A white circle (○) outside the whisker was an outlier. A multi-analysis was performed using the Bonferroni approach. The significant level was $p<0.05/15=0.0033$. The marks of ＊ shown in Fig. 5 represent comparisons which were judged to have significant differences.

4. Discussion

This study performed identification experiments and questionnaire surveys to clarify how designs, colors and layouts on the short-sides of pharmaceutical packaging boxes, in which tablets with press through packages (PTP) were contained individually, affected the identification of pharmaceutical products. The identification experiments were assigned a time limit and subjects were assigned to identify items within the given time, simulating to open a drawer in a dispensing cabinet in a pharmacy and prepare drugs as quickly as possible during dispensing activities. Subsequently, the achievement ratios for four sample sheets were compared regarding the number of subjects who found the designated products within the given time. The experimental results were as followed: The ratio for sample sheet I was 28.9%, where one color and one design pattern were used. Sample sheet II ratio was 36.7%, where one color was used but every article had corresponding design patterns. This suggested that design patterns influenced identification. Furthermore, the ratio in sample sheet IV, where in addition, different colors for each article are used to distinguish articles, was 37.8%. This result of sample sheet IV was almost equivalent to that of sample sheet II. The achievement ratio of sample sheet III, where design patterns are identical and colors are different corresponding to each article was 47.8%. Approximately half of the subjects were able to find the designated item for sample sheet III. Although sample sheet III had as simple a design pattern as sample sheet I, not only articles are distinguished due to band but also content size specifications are emphasized. Consequently, the subjects were able to identify the designated item within a shorter time, as this study suggested. Judging these results, it was suggested that information based on colors and layout with emphasis on specification indications greatly influenced identification. The experiments of this study observed that color for each article was more effective than design patterns for each article to distinguish products. Furthermore, the experiments observed that for distinction of products, the effectiveness of both colors and design patterns was the same as design patterns alone. An appropriate quantity of information must be considered to identify a pharmaceutical product as quickly as possible from a large number of products stored in a drawer of the cabinet.

The questionnaire survey for 406 research participants provided adequate time for the pharmacists to consider and answer questions, unlike the experiments, in which a participant may feel hurried due to a time limit. Identifications of information on the short-sides of pharmaceutical packaging boxes were examined via this survey where participants were able to judge without hurry. The compared identifications of four design types on the short-sides of packages showed that Design C had a significantly high median value; not only design patterns were different for each article but also colors were different for each specification. The results of the survey confirmed that Design C was chosen as the most distinguishable design. The main reasons that Design C was most easily identified were “conspicuous”, and “subjects were able to recognize that products were classified by each article and each specification”. These answers accounted for approximately 30% (119 in 406 subjects). It was suggested that Design C enabled

the prevention of dispensing errors regarding wrong content types of specifications, and the identification of the correct pharmaceutical products, because of not only a distinguishable design to recognize the same article but also effective color classifications on specification indications. Design B gained the second highest scores next to Design C. The reasons for the choice of Design B were "conspicuous" and "subjects were able to recognize the same article", as a large number of participants answered. However, "as articles have the same color, the specifications seemed to be easily mistaken" was observed in a large number of answers to Design B. From these viewpoints, it is required to develop ingenuity on design including color classifications corresponding to articles and color layout for indications of specification parts. The present research showed the participants nine pharmaceutical product items in a manner of three articles and three specifications and they were able to afford the time to consider the items. Consequently, this research suggested that both design- and color-related distinctions based on article types enhanced identifications of participants in comparison with color-related distinction based on article types. Further studies require examinations and verifications to develop design methods for the usages of colors and layouts focusing on specification parts and to observe how identifications are affected in practical settings of pharmacies via experimental methods.

Next, (f) obtained the significantly highest median values as the identification of specification in the questionnaire survey. In this design (f), colors are different based on the content quantity type and all specifications are indicated in the layout designs, which resulted in subjects' choice to identify specifications most distinctively. The main reasons that the specification design of (f) was best, were "all specifications are recognized" and "it helps to notice that the article has other specifications". The ratio of these reasons was approximately 43% (175 in 406 subjects). It was suggested that indications of multiple specifications enabled subjects to cognize the presence of other specifications and be more cautious in distinctions of specifications. As a result, the design (f) is effective to prevent dispensing errors, as was considered. When pharmacists know the presence of other specifications, and find that some products are not prepared in the institution they belong to, they could suggest new prescriptions. Furthermore, the questionnaire regarding the necessity of the indications of multiple type speculations confirmed that 50% of the subjects, pharmacists, answered "necessary". Including the answers of "somewhat necessary", 88% of pharmacists in the survey found a necessity of indications for multiple-type specifications. The study of Sato et al. [9] regarding PTP sheets reported that dispensing errors occurred frequently in pharmaceutical products with two specifications compared with that with single specification. Thus, the identification of specifications is an important factor to reduce risk factors of picking up errors. The present study employed three types of indication methods for multiple specification types: "arrow symbols placed over and/or under specification mark: sample sheet (d)", "large, medium and small circle symbols: sample sheet (e)" and "all specifications are inscribed: sample sheet (f)". It is considered that symbols such as arrow and circle symbols are unlikely to convey our intentions if they are not accompanied by written explanations. We continue to examine distinctions of symbols,

balancing in whole information and coloring methods to develop effective indication methods which enhance indications of pharmaceutical products.

This study confirmed that the color-related classification based on articles was supportive in regard to identification of articles. However, it was suggested that approaches to identify differences in specifications are required using not only coloring methods but also design pattern methods. In addition, it was suggested that display methods were necessary to enable pharmacists to perceive the presence of other specifications. Sato et al. [9] also have suggested similarly, regarding design studies of PTP sheets with different specifications. Most pharmacists considered that identifying specifications were particularly significant. Furthermore, dispensing errors due to mistaken identification regarding specifications have occurred frequently, as were reported in the Incident Collection and Analysis Project of "Hiyari-hatto". Therefore, we must immediately develop countermeasures. The present study would make a contribution to develop and create pharmaceutical packaging with designs capable of identifying products. We continue to examine how design layouts on the short-sides of packages affect distinctiveness in pharmaceutical products and dispensing errors of picking incorrect products, while taking utility model rights and design right into consideration. The further study would lead to a pharmacy practice setting for pharmacists to provide medicine safely to patients.

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Conflicts of Interest：COI

Kohei Miyaso is an employee of Toyama Sugaki Co., Ltd.

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