

ความชุกและการปฏิบัติตามกฎหมายของเนื้อหาจลาจลและโฆษณาของผลิตภัณฑ์เสริมอาหารที่อ้างว่าเสริมสมรรถภาพทางเพศชายบนเว็บไซต์

Prevalence and Legal Compliance with Labels and Advertisement of Nutritional Supplement Products with Male Sexual Performance Enhancement Claims on Websites

นิพนธ์ต้นฉบับ

Original Article

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บทคัดย่อ

วัตถุประสงค์: เพื่อระบุจำนวนและสัดส่วนของของผลิตภัณฑ์เสริมอาหาร ยาและเครื่องสำอางที่กล่าวอ้างว่าเสริมสมรรถภาพทางเพศชายที่โฆษณานบนเว็บไซต์ และระบุสัดส่วนและจำนวนของผลิตภัณฑ์เสริมอาหารที่ปฏิบัติตามกฎหมายด้านการแสดงเลขสารบบอาหาร, สารสำคัญ, ฉลาก, การแสดงค่าเตือน และการโฆษณา วิธีการศึกษา: การศึกษาเชิงพรรณนาโดยเก็บข้อมูลครั้งเดียว สืบค้นข้อมูลผลิตภัณฑ์ที่อ้างว่าเสริมสมรรถภาพทางเพศชายที่โฆษณานบนเว็บไซต์ สืบค้นบน Google™ เลือกเฉพาะผลิตภัณฑ์ชื่อการค้าที่ไม่ซ้ำกัน สืบค้นซ้ำสามครั้งในช่วงมิถุนายน-สิงหาคม 2560 นักวิจัยสองคนประเมินข้อมูลอย่างอิสระแล้วนำมาผลมาเปรียบเทียบกัน โดยแจกนับผลิตภัณฑ์เสริมอาหาร ยาและเครื่องสำอางที่กล่าวอ้างสรรพคุณดังกล่าว ส่วนผลิตภัณฑ์เสริมอาหารนั้นได้ประเมินตามการปฏิบัติตามกฎหมายด้านการแสดงเลขสารบบอาหาร, สารสำคัญ, ฉลาก, การแสดงค่าเตือน และการโฆษณา โดยใช้กฎหมายที่เกี่ยวข้องเป็นเกณฑ์ ผลการศึกษา: ในผลิตภัณฑ์ที่อ้างสรรพคุณดังกล่าวทั้งหมด 210 ผลิตภัณฑ์ ส่วนมากเป็นผลิตภัณฑ์เสริมอาหาร (155 ผลิตภัณฑ์หรือร้อยละ 73.81) ในบรรดาผลิตภัณฑ์เสริมอาหาร ส่วนมากพบว่าเลขสารบบอาหารตรงกับที่แสดงในฐานข้อมูลของสำนักงานคณะกรรมการอาหารและยา (ร้อยละ 74.20) ใน 42 ผลิตภัณฑ์ที่ข้อมูลบนภาพฉลากเพียงพอต่อการประเมิน พบว่าหัวข้อในฉลากที่ปฏิบัติตามกฎหมายมากที่สุดคือ แสดงเลขสารบบอาหาร และคำแนะนำการใช้ (ร้อยละ 100 ทั้งคู่) ส่วนใน 113 ผลิตภัณฑ์ที่ต้องใช้ข้อมูลอื่นบนเว็บไซต์ร่วมประเมินด้วยนั้นพบเรื่องการแสดงปริมาณที่บรรจุมากที่สุด (ร้อยละ 90.26) มีผลิตภัณฑ์เสริมอาหารเพียง 31 ผลิตภัณฑ์ (ร้อยละ 20.00) ที่มีส่วนประกอบที่ต้องแสดงค่าเตือน แต่ส่วนมากมักไม่แสดงค่าเตือน (ร้อยละ 87.10) ผลิตภัณฑ์ส่วนมากแสดงข้อมูลชื่ออาหารในการโฆษณา (ร้อยละ 68.39) สรุป: พบว่าผลิตภัณฑ์เสริมอาหารมีมากที่สุดเมื่อเทียบกับยาและเครื่องสำอางที่กล่าวอ้างว่าเสริมสมรรถภาพทางเพศชายบนเว็บไซต์ และการปฏิบัติตามกฎหมายด้านฉลากและการโฆษณายังบกพร่องหลายประเด็นหน่วยงานที่เกี่ยวข้องควรเพิ่มการเฝ้าระวังติดตามควบคุมให้เป็นระบบมากขึ้น และให้ความรู้แก่ผู้บริโภคมากขึ้น

คำสำคัญ: ผลิตภัณฑ์เสริมอาหาร, ยา, เครื่องสำอาง, เสริมสมรรถภาพทางเพศชาย, เว็บไซต์, ฉลาก, ค่าเตือน, โฆษณา

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Abstract

Objective: To determine proportions of nutritional supplements, drugs and cosmetics with male sexual enhancement claims on websites and proportions of nutritional supplements with the claim of their compliance with related laws and regulations regarding registration number, ingredients, labels, warning, and advertisement. **Method:** In this cross-sectional descriptive study, data of products (nutritional supplements, drugs and cosmetics) with the claim were search on Google™ three times within three months (June – August 2017). Only products with different tradenames were retained. Data were evaluated independently by two researchers and combined after comparisons and agreements. Each of the three types of products were tabulated. For nutritional supplements, their compliance with related laws and regulations were tabulated. **Results:** Of 210 products with the claim, 155 of them were nutritional supplements (73.81%). Of the 155 nutritional supplements, registration number complied the most (74.20%). Of the 42 products with adequate information from label for valuation, registration number and use instruction complied the most (100.00% for both). Of the 115 products with the additional information from the website, content amount complied the most (90.26%). Only 31 products (20.00%) had ingredients requiring warnings but most of them did not do so (87.10%). For advertisement, most products presented their product names (68.39%). **Conclusion:** Among products with male sexual enhancement claim on website, nutritional supplements were found the most compared with drugs and cosmetics. Compliance with laws and regulations regarding labels and advertisement was not at an adequate level. Responsible agents should put more effort on systematic vigilance on the products and education for the consumer.

Keywords: nutritional supplements, drugs, cosmetics, male sexual performance enhancement, website, labels, warnings, advertisement,

Journal website: <http://ejournals.swu.ac.th/index.php/pharm/index>

Introduction

Nutritional supplement products have been in a rising popularity. In addition to nutritional and health benefits, other

purposes including male sexual performance enhancement are also expected by certain customers. In online world or

social media, the advertisement of nutritional supplement products with male sexual performance enhancement claim has been more prevalent; however, compliance with laws of these advertisements has not been known. As a result, to tackle the problems of illegal labels and advertisement of these products could not be handled properly. The problems associated with these products have been increasing with the increased prevalence of erectile dysfunction with the rise of elderly population. Thus, the legal compliance problem of labels and content of advertisement of nutritional supplement products with male sexual performance enhancement claim needs to be systematically studied.

Erectile dysfunction (ED) is more prevalent with the older age population. ED affects both the patient and his spouse. Based on a survey in 2000, 37.5% of Thai men aged 40 – 70 years old were affected by ED.¹ In 2003 – 2013, 83.3% of Thai men older than 60 years old were affected with ED and the risk was higher with diabetes or impaired kidney function which increased with age.²

In addition to the use of medications such as sildenafil, tadalafil and vardenafil, other products have been used for ED. Thai traditional drugs, cosmetics, and nutritional supplements have been used for the purpose of male sexual performance enhancement including more numbers of sexual intercourse, prolonged sexual intercourse, and delayed ejaculation. The use of drugs, cosmetics or nutritional supplements is easier and more convenient than devices such as vacuum erection device and surgery for ED. These products could be purchased from various channels including drug stores, grocery stores, convenience stores, entertainment centers, and online, websites, and social media.³

Illegal use of sildenafil, tadalafil and vardenafil has been more prevalent. There has been more news of drug tampering or adulterating with other products including foods, food supplements, cosmetics, Thai traditional drugs, and nutritional supplements.^{4,5} Adverse effects of sildenafil including arrhythmia, painful erection (priapism), and sudden death of acute heart have been in the news.⁶⁻⁸ Products tampered with any of these substances (sildenafil, tadalafil and vardenafil) could also pose such harms.

Smuggling production of drug products (sildenafil, tadalafil and vardenafil) and tampering other products with these drug substances could be heightened by more convenient access without prescription. Various channels to distribute these

products including the Internet have been growing for convenient access. Some men turned to non-drug products because of fear of the prescription drugs for ED. However, the use of these non-drug products might not free from the harm of the actual ED drugs like sildenafil.

Tempering or adulterating sildenafil in nutritional supplement products is not known to the customers. The Department of Medical Sciences has reported sildenafil tampered in nutritional supplement products and drug products. A report revealed some brands of nutritional supplement with sildenafil tampering including Double Maxx[®], ABM Max 888[®], CKK Plus[®], and Big Boom[®] cordyceps and ginseng product.⁹ It could be expected that nutritional supplement products with and without sildenafil tampering could be more prevalent over time. There have been no systematic studies on sildenafil tampering on nutritional supplement products. However, there should be studies on to determine numbers and proportions of drug products, nutritional supplement products, and cosmetic products with the claim of male sexual performance enhancement.

The advertisement of male sexual performance enhancement of nutritional supplement products is considered illegal according to the Notification of the Food and Drug Administration on Food Advertisement Rules B.E. 2551 (2008).¹⁰ This rule defines five types of statements and visuals that cannot be used in advertisement of food products which could be applied to nutritional supplement products. One of the five types of statements is statements that indicate or imply the benefits of sexual enhancement, sexual pleasure, or sexual intercourse, for example, nourishing and boosting sexual performance, boosting male and female sexual performance, food supplements for men and women, boosting sex organ size, boosting breast size/sizing up the breast, and tightening the vagina. Advertisement of nutritional supplement products is under the law governing food product advertisement.

In addition to food and nutritional supplement products, health products with the illegal claim of therapeutic benefits and sexual enhancement of health products have also been reported. In the fiscal year 2015, the Thai Food and Drug Administration (FDA) revealed law suits of 2 websites claiming therapeutic benefit and sexual performance enhancement of health products.¹¹ These lawsuits were based on occasional arrest so it has been difficult to estimate the number and proportion of each type of products that broke the law by

overclaiming the benefits of the product. Prosecution on illegal health products which included nutritional supplement products. Wrongdoing included products with no registration number, food registration number (for food and nutritional supplement products), fake or counterfeit food registration number^{12,13} and online advertisement of counterfeit nutritional supplement products.¹⁴

Products with no, or with fake or counterfeit registration number is the root of most subsequent problems. They indicate the defective vigilance and monitoring process that allows illegal products and claims that could harm the health of the public. There have been no studies systematically determining legal aspects other than advertisement have been breached and in what proportion. In addition, legal nutritional supplement products could contain ingredients that are harmful to individuals through interactions with certain drugs. For example, foods and substances that could potentiate the risk of more bleeding of warfarin are ginseng, cordyceps, fish oil, and ginko biloba leaves.¹⁵ Therefore, compliance with label and advertisement laws, and components in the product that need cautions with use should be known so that vigilance and legal control on health products could be more effective.

With the concern of harm associated with health products with the claim of male sexual performance enhancement especially nutritional supplement products, there is a need to determine the extent of the problem including number and proportion of nutritional supplement products, cosmetics, and drugs with the claim on the website. Among those nutritional supplement products, compliance with laws of labels and advertisement should be determined.

In this study, specific objectives were to determine 1) number and proportion of drug products, cosmetic products and nutritional supplement products with the claim of male sexual performance enhancement on website, 2) proportion of nutritional supplement products on website with male sexual performance enhancement claim that were compliant with the law of food registration number, 3) number and proportion of substances in the nutritional supplement products with the claim of male sexual performance enhancement on website, 4) compliance with the laws of 4.1) labels, 4.2) warnings, and 4.3) advertisement of nutritional supplement products with claim of male sexual performance enhancement on website. The findings could be useful for healthcare providers as basic information for educating the public and for agents that are responsible for monitoring these products (e.g., FDA and

provincial health administration office) to be able to make policy and monitor the products more effectively.

Definitions

This study included nutritional supplement, drug and cosmetic products with the claim of male performance enhancement found on the website. **Male sexual performance enhancement products** were defined as products with the claim of erection maintenance adequate for vaginal penetration which leads to proper ejaculation and sexual intercourse satisfaction. This definition was based on the term **erection dysfunction (ED)** which was referred to the inability of penile erection and or the rection not long enough to achieve sexual intercourse pleasure¹⁶ and based on **premature ejaculation** which was referred to the ejaculation before vaginal penetration or within 1 minute after penetration.¹⁷ Therefore, **nutritional supplement products with male sexual performance enhancement claim** was defined as any nutritional supplement products with the content on the label indicating or implying that the benefit of enhancing male sexual performance, maintaining penis erection, delaying ejaculation, or any contents with similar meaning, but not those with only the benefit of arousing sexual desire, or enlarging penis size.

In identifying all study products, **drug products** was defined based on Drug Act B.E. 2510 (1967)¹⁸ while **cosmetic products** were based on Cosmetic Act B.E. 2558 (2015).¹⁹ For nutritional supplement products, the identification was based on the Notification of the Ministry of Public Health (No. 293) B.E. 2548 (2005) on Nutritional Supplement Products²⁰ and the Notification of the Ministry of Public Health (No. 309) B.E. 2550 (2007) on Nutritional Supplement Products (No. 2).²¹ Thus, **nutritional supplement products** were defined as any products with the intention other than normal food consumption containing foods or food components in the form of tablets, capsules, powders, pellets, liquids or other forms which are not used as conventional foods for consumers who expect the benefit of health promotion. Foods or food components were referred to (1) vitamins, amino acids, fatty acids, minerals and plant or animal products, (2) concentrates, metabolites, components or extracts of (1), (3) synthetics of (1) or (2), (4) mixtures of any of (1) (2) or (3), (5) any other substances defined as nutritional supplement products by the FDA.

In this study, **labels** were defined as pictures of label or texts on the pictures of labels on the product package on the website. **Content on website** was defined as pictures, video clips, or any texts other than picture or video clips presented on the website. For **advertisement**, it was defined as any acts presented to the public by means of sight, hearing, or any perception of the information for the commercial benefit including the presentation of text or pictures on the website. This definition was based on the Consumer Protection Act B.E. 2522 (1979) which defines labels as pictures, trademarks, symbols, or any texts presented on product container or package, and as documents or manuals accompanying the product, signs installed or demonstrated on products, product container or package.²² Labels were composed of 11 components. Since nutritional supplement products are legally registered as food products, they are under any regulations similar to those of foods, and certain additional regulations for nutritional supplement products. Criteria for assessing compliance with the law of labels of nutritional supplement products were based related laws^{20,21} and are as follows. Labels of nutritional supplement products had to be presented in Thai language, with or without foreign languages, and be compared with these 11 components.

(1) name of the food product has to be specified with “nutritional supplement product.”

(2) food registration number consists of trademark and the registration number, and the number was verified with the database of the Thai FDA website²² by the researcher.

(3) name and location of the manufacturer or importer, as needed, (3.1) for domestic products, name and location of manufacturer or re-packager (3.2) for imported products, name and location of importer and the country of manufacturer.

(4) amount of content in the package, (4.1) presented as number of units for products in tablet or capsule form, (4.2) net volume for liquid form, and (4.3) net weight for solid form or others.

(5) components and content of each component with claimed benefits on the label.

(6) the presence of the recommendation of “five food groups should be regularly consumed with proper proportions.”

(7) the presence of “no preventive or therapeutic benefit” with bold letters and contrast background.

(8) recommendation on its use.

(9) recommendation on its storage (if any).

(10) expiration date with “expiration date” or “consume before.”

(11) warnings for each component if mandated by laws regarding health claim and warning. All products must be warned with “not for children and pregnant women” and warnings for each component as mandated by laws which are categorized into three levels as follows.

- components not requiring warning by laws.
- components requiring warning by laws.
- components requiring warning by laws but not presenting on the label.

Components that are mandated to present warning are based on the Notification of the Ministry of Public Health (No. 293) B.E. 2548 (2005) on Nutritional Supplement Products²⁰ and the Notification of the Food and Drug Administration on the Ministry of Public Health announcement (No. 294) B.E. 2548 (2005) on royal jelly and royal jelly products.²³ Some examples of components with mandatory warnings are as follows: shark cartilage “not for patients with heart diseases and post-operative rehabilitation,” royal jelly and royal jelly products “not for patients with asthma or allergy because of possible severe allergy,” chitosan “not for children, pregnant women, and breast-feeding women,” “those taking fat-containing nutritional supplement should take the product 2 hours before or after chitosan” and “be cautious in patients with sea food allergy or with underweight,” fish oil “it is contraindicated for patients with sea fish allergy or fish oil” and “be cautious in patients with prolonged coagulation or those using anti-coagulant or aspirin,” evening primrose “it is contraindicated in patients with seizure history” and “be cautious in patients taking anti-epilepsy drugs,” fiber “to prevent intestinal obstruction from dry fiber, 1 – 2 glasses of water should be taken,” extract of ginko biloba leaves and products containing gink biloba leaves “blood clot may be prolonged,” and ginger or ginger extract “not for patients with gallstone.”

For **advertisement of nutritional supplement products**, it was defined as 7 components based on laws regarding advertisement of foods^{24,25} which was different from label analysis which was judged only as compliant or not. Seven components for nutritional supplement products are as follows.

(1) **The presence of benefits, quality or use** of the food must be of the whole formula not each component. Benefit

must not be misled, false or overclaimed. Advertisement must not indicate or imply that the food has therapeutic, preventive, or curative benefit, or could alleviate disease risk, improve immunity, reduce weight, get rid of fat, control weight or fat, reduce fat absorption to improve body size, unless the food for weight control, or enhance sexual performance.

(2) **Food name** must not misleading in the components, false, or deceptive which could cause false beliefs or conflicts with Thai culture.

(3) **Pictures in the advertisement media** cannot be brain images or any pictures implying the brain, heart, lung, liver or any other internal organs, or before-after images such as fat-thin persons, and dark-fair skinned persons.

(4) **The advertisement texts or words** must not compare the product with others or despise other products.

(5) **The warning** "read warnings before use."

(6) **The warning** "no preventive or therapeutic benefit."

(7) **prohibition in advertisement content** included 1) false or overclaiming content, 2) content indicating or implying therapeutic, alleviating, curative or preventive benefit of the product, 3) content indicating structure and function modifying effect on organ or the whole body of the product, 4) content indicating sexual enhancement, sexual pleasure, or sexual intercourse benefit of the product, 5) content indicating skin nourishing or beauty benefit of the product, 6) content indicating weight reduction, obesity reduction benefit of the product, except the product registered as foods for weight control in accordance with the for Notification of the Ministry of Public Health No. 12 B.E. 2532 (1989) on foods for weight control, 7) content indicating body shape improving, fat trapping benefit of the product, and 8) advertisement referenced with academic report, or statistics that were not approved by the FDA.

Methods

In this descriptive study with cross-sectional design, the first objective of determining numbers and proportions of products on website with male sexual performance enhancement included nutritional supplement, cosmetic, conventional drug, Thai traditional drug, herbal drug products. However, for the rest of the objectives, only nutritional supplement products were included. The study evaluated the compliance with laws regarding labels and advertisement on registration number, food components, labels and

advertisements. Both legal and illegal products were included. The study did not evaluate narcotics, psychotropics, and sexual enhancement devices. The study was conducted from June to August 2017 which could not fully reflect the present situation of 2021. However, the finding at the conduct time could be used for a basis for forecasting the use of the product which is in the increasing popularity ever.

Study population and sample

Study population was nutritional supplement products claiming male sexual performance enhancement on the website which was reached by Google™ search engine. Study sample was the population products searched by Google™ search engine using selected search keywords and were the brand name firstly found from the search. Unit of analysis of the study was products with non-redundant brand names found between June and August 2017.

Sample size estimation

Since the population size of nutritional supplement products with the claim of male sexual performance enhancement on the website was not known, a conservative approach to estimate the sample size was used assuming the large population size, and unknown variance of the proportion of the variable of interest. Based on the equation of $n = Z^2 \cdot p \cdot q / e^2$ ²⁶, with a type I error of 5% ($Z = 1.96$), p and q of 0.5 offering the highest variance, and a sampling error or precision of 5% ($e = 0.05$), a sample size of 385 non-redundant trade name products was needed.

Inclusion and exclusion criteria

The sample was selected using the convenience sampling method. Each of unit of analysis was selected using Google™ search engine because it has been the most popular platform. The search was conducted from June to August 2017, and each unit of analysis was selected in chronological order of its presence of the website search result pages. No random selection or skipping was used which was in accordance with the consumer's searching behavior. Products with non-redundant trade names firstly found were included.

Websites with trade name products of drugs, cosmetics and nutritional supplement products following definitions of products with the claim of male sexual performance enhancement stated previously were selected. Their labels had to indicate or imply more numbers of sexual intercourse,

prolonged sexual intercourse, or delayed ejaculation, but not merely enhancing sexual arousal or penis size. Keywords for searching was in Thai languages which are mostly used by Thai consumers. Based on the trials by the researcher, these 9 main keywords provided the highest number of preliminary search results of the study products. These 9 main Thai keywords included drugs for male nourishment, male food supplements, drugs for premature ejaculation, Viagra, sex enhancing drugs, drugs for men, drugs for male sexual enhancement, products for gentleman, and cream for the penis and their related variations. These 9 words and their variations resulted in a large number of websites that offered a saturated information, i.e., redundant trade name products. For example, the use of the keyword “drugs for male sexual performance enhancement” resulted in 624,000 websites of redundant trade name products, while variations of the term including “drugs for male enhancement, drugs for male sexual, drugs for male sexual performance, drugs for male performance, drugs for male performance enhancement, drugs + performance enhancement + male, enhancing drugs + performance + gender + male” and “drugs to enhance male sexual performance” resulted in 500,000, 431,000, 272,000, 169,000, 609,000, 609,000, 609,000 and 2,930 websites, respectively. Other main keywords also resulted in a large number of websites. The search was stopped once the information was saturated, i.e., no new non-redundant trade name products were found.

In Google™ search, 20 website links (or URLs) were listed in a given result page. The researcher examined each result page until redundant trade name products or no study product were found. It was found that no study products or redundant trade name products were found at 8 – 9 result pages (or about 200 sites or URL links). The researcher performed searching once a month from June to August 2017. For a given selected website, only study products with clear pictures of labels and texts were selected. The product could have only picture of the label or with advertisement texts on the website. The picture of the label could be only one, not all sides of the package. For exclusion criteria, products with advertisement texts but no picture of the label or products with visually unclear picture of the label, despite the search results from other pages were excluded.

Evaluation of compliance with laws regarding labels, warnings, and advertisement of nutritional supplement products with male performance enhancement claim on website

In assessing compliance with laws regarding labels, warnings, and advertisement of nutritional supplement products with male performance enhancement claim on website, two searchers worked independently (MT and NR) and compared their evaluation results. Any disagreements were discussed and conclusions were made; if not, an expert in related laws and regulations of foods and drugs were consulted for the final decision.

For the first study objective, numbers of eligible drug products, cosmetic products, and nutritional supplement products were identified. Their registration numbers were verified against those in the database of the Thai FDA website.²⁷ Products with compliance of the products regarding registration number laws were counted. Components or substances in the nutritional supplement products were identified and counted.

In assessing compliance with the laws regarding labels, content presented on the picture of the label was evaluated using the criteria defined previously. To reflect the information the consumer would receive from the picture on website which is not the from the actual product package, label information evaluation consisted of two methods. In the first method, the evaluation was based on the labels with complete information found on the picture of the label of the product package. The second method was applied when the information on the picture of the label was incomplete, and content of advertisement on the website was needed for evaluation. This could happen because some pictures showed only one side of the product package. Pictures from other websites were not searched to complete the missing label information to reflect the information the consumer actually see from the website. However, the absence of certain components of the label did not mean the product did not have such component presented on their label, but it meant that the website did not present the component.

For compliance of warning on the label, warning statements for each of the components were identified and compliance with mandatory presentation of such warnings was verified. Finally, evaluation of compliance with laws regarding advertisement was conducted according to the criteria described previously.

Ethical considerations

The study protocol was approved by the Ethics Committee of Faculty of Pharmacy, Srinakharinwirot University (approval number: 013/M2560; approval date: March 21, 2017). The study had a low ethical risk because it used content presented to the public on the website. No product trade names were recorded in analysis and summary statistics of types of products, not individual products or individual websites, were presented as the result.

Data analysis

The results were presented using descriptive statistics including frequency with percentage of each type of products (i.e., nutritional supplements, drugs and cosmetics) and nutritional supplement products with compliance with laws of labels and advertisement.

Results

From the Google search from June to August 2017, 210 non-redundant trade name products of drugs, cosmetics and nutritional supplements were eligible for the evaluation. On the 8 – 9 search result pages (i.e., 160 – 180 URL links), more than half of the websites listed were irrelevant to the study products. At about 80th – 90th URL links, 1 to 11 non-redundant trade name products were found. Of the 210 eligible products, about three-quarters were nutritional supplements (155 products or 73.81%), followed by cosmetics, Thai traditional drugs, and conventional drugs (20, 18 and 17 products or 9.52%, 8.57% and 8.10%, respectively).

In terms of compliance with the registration number law of the 155 nutritional supplement products when verified against the database of the Thai FDA website, 115 products (74.20%) had the correct registration number, while 14 products (9.05%) had incorrect registration number and 26 products (16.77%) did not show the registration number on the website.

Among 155 nutritional supplement products, 134 substances or ingredients were listed. The five most frequently found substances or ingredients were ginseng extract (85.81% of the 155 products), followed by cordyceps extract (60.00%), oyster extract (48.39%), L-arginine (47.10%) and black ginger extract (41.29%) (Table 1).

Table 1 Substances or ingredients found in 155 nutritional supplement products.*

Substances or ingredients	Number of products	%
Ginseng extract	133	85.81
<i>Cordyceps sinensis</i> extract	93	60.00
Oyster extract	75	48.39
L-arginine	73	47.10
Black ginger extract	64	41.29
Zinc amino acid chelate	47	30.32
Lingzhi extract	43	27.74
Goji berry, wolfberry	30	19.35
<i>Ginkgo biloba</i> Leaf extract	29	18.71
<i>Angelica sinensis</i> extract	19	12.26
Vitamin B6	18	11.61
Selenium	17	10.97
Horny goat weed	16	10.32
Coenzyme Q10	15	9.68
<i>Tongkat ali</i> extract	14	9.03
Vitamin E	13	8.39
Beta-glucan	12	7.74
Vitamin C	12	7.74
Vitamin B3	12	7.74
Maca	11	7.10
Garlic extract	11	7.10
Pine bark extract	11	7.10
Black pepper extract	10	6.45
Hawthorn	9	5.81
Taurine	8	5.16
Grape seed extract	8	5.16
<i>Tribulus terrestris</i>	8	5.16

* A total of 134 substances or ingredients were found in 155 products and only substances or ingredients found in 5% of the products were listed in the table.

Compliance with laws regarding labels, warnings, and advertisement of nutritional supplement products with male performance enhancement claim on website

Of the 155 nutritional supplement products, 42 of them had complete information from the picture of the label (27.10%) while 113 products (72.90%) needed additional information from the texts on the website for evaluation. Of the 42 products with complete label, label components complying the most with the law were registration number and recommendation on the use (100% for both), followed by food components and their content (97.62%), name location of manufacturer (95.24%), and food name and content amount (92.86% for both). Label components with the least compliance were recommendation for storage (if any) (47.62%), month and year of manufacturing and expiration (69.05%), and warning "take all 5 food groups regularly with proper proportion" (73.81%) (Table 2).

Table 2 Compliance with laws on labels of 42 nutritional supplement products with complete information from the picture of the label.

Presence of components	N	%
Product name ('nutritional supplement product' presented as the part of the name)	39	92.86
Registration number	42	100
Name location of manufacturer	40	95.24
Content amount	39	92.86
Components and their content amount	41	97.62
Recommendation on use	42	100
Recommendation on storage (if any)	20	47.62
Month and year of manufacturing and expiration	29	69.05
Warning – not for children or pregnant women	34	80.95
Warning – take all 5 food groups regularly with proper proportion	31	73.81
Warning – no preventive or therapeutic benefit	36	85.71

Of the 113 nutritional supplement products with additional information from the texts on the website was needed for evaluation, the most found component was content amount (90.26%), followed by recommendation on use (84.07%), and registration number (76.10%) (Table 3). The least presented component was month and year of manufacturing and expiration (4.42%), followed by warning “no preventive or therapeutic benefit” (12.38%), recommendation on storage (if any) (13.27%), warning “not for children or pregnant women” (25.66%), warning “take all 5 food groups regularly with

Table 3 Compliance with laws on labels of 113 nutritional supplement products with additional information from the texts on the website was needed.

Presence of components	N (%)			Total
	Presented on label	Presented as texts on website	Presented on label and as texts on website	
Product name ('nutritional supplement product' presented as the part of the name)	24 (21.24%)	24 (21.24%)	22 (19.47%)	70 (61.95%)
Registration number	5 (4.42%)	63 (55.75%)	18 (15.93%)	86 (76.10%)
Name location of manufacturer	8 (7.08%)	0	0	8 (7.08%)
Content amount	19 (16.81%)	38 (33.63%)	45 (39.82%)	102 (90.26%)
Components and their content amount	7 (6.19%)	31 (27.43%)	4 (3.54%)	42 (37.16%)
Recommendation on use	4 (3.54%)	81 (71.68%)	10 (8.85%)	95 (84.07%)
Recommendation on storage (if any)	2 (1.77%)	11 (9.73%)	2 (1.77%)	15 (13.27%)
Month and year of manufacturing and expiration	5 (4.42%)	0	0	5 (4.42%)
Warning – not for children or pregnant women	7 (6.19%)	20 (17.70%)	2 (1.77%)	29 (25.66%)
Warning – take all 5 food groups regularly with proper proportion	4 (3.54%)	25 (22.12%)	1 (0.88%)	30 (26.54%)
Warning – no preventive or therapeutic benefit	6 (5.31%)	7 (6.19%)	1 (0.88%)	14 (12.38%)

proper proportion” (26.54%), and components and their content amount (37.16%) (Table 3).

In terms of compliance with law regarding **warnings** on the label, of the 155 nutritional supplement products, 124 products (80.00%) had no substances or ingredients that need warnings; while the rest 20.00% did so. Of the 20 products, only 4 of them (12.90%) had the warning in place while 27 of them (87.10%) showed no or incomplete warnings.

Finally, compliance with laws of **advertisement**, product name was the component that complied the most (106 of 155 nutritional supplement products, or 68.39%), followed by the picture of the advertisement (54.84%), prohibition for advertisement (48.39%), words or texts of advertisement (21.94%), warnings of “read warning before use” and “no preventive or therapeutic benefits” (12.90% and 10.32%, respectively). Components with compliance from no products was the presence of benefits, quality or use of the product which was consistent with the study inclusion criteria.

Discussions and Conclusion

In this cross-sectional descriptive survey study on the 210 products with the claim of male performance enhancement searched by Google™ from June to August 2017, most of them were nutritional supplements (155 products or 73.81%), followed by cosmetics, Thai traditional drugs, and conventional drugs (20, 18 and 17 products or 9.52%, 8.57% and 8.10%, respectively).

With the highest proportion of 73.81%, this indicates that nutritional supplement products have been in the increasing popularity with the expectation of male sexual performance enhancement benefit. With more trade name products available, the extent of problems relating to this product in the market is sizable, but the exact number has not been known. In each of the reports of the Thai FDA showed that only 10 – 20 nutritional supplement products had the claim of male sexual performance enhancement.^{28,29} This could be because these reports were done with respect to occasional complaints. Our present study was the first systematic research covering the large population of the products on the Internet; hence a relatively large number of the products with the claim was found on the website. It is recommended that more systematic studies be conducted to improve vigilance and monitoring on the trend of nutritional supplement products

with such claim and the problem could be prevented and solved in a timely fashion.

In this study, the search for the products was done through Google™. Therefore, certain products only on other platforms such as social media of Facebook and Instagram could have been missed. With a total of 210 non-redundant trade name products found, representativeness of the whole population of the nutritional supplement products with the claim of male sexual performance enhancement by our study could be somewhat limited. However, once the actual searching behavior of the consumer is considered, our study represents such behavior. With the actual browsing of only the URLs listed in the first 1 – 2 result pages, most products were also found in such URLs.

It was found that only 74.20% of nutritional supplement products had the correct registration number, while 14 products (9.05%) had incorrect registration number and 26 products (16.77%) did not show the number on the website. Despite no direct adversities from this extent, there should be a 100% compliance. This imperfect compliance indicates ineffective vigilance and monitoring system, and defective law enforcement. More law non-compliance could mean more chances of harms from the products. However, products with no registration number could be the ones with the number but not presented on the website. Our study could have certain errors. More studies should be done to search for registration number of given products from other websites, or to use their trade names to search for their registration number. More accurate data could be obtained. However, since this study aimed at representing the view of the consumer in their actual search for the product, additional search for registration number of those with registration number absence was not conducted.

Ginseng extract was found the most in 155 nutritional supplement products (85.81%), followed by cordyceps extract and black ginger extract, respectively. These components have been believed to have male sexual performance enhancement benefit. However, products with and without information of components on the picture of the label were included in the study. This kind of information could be different from what the consumer could see on the label of the actual products. Our finding could be different from the action information on the actual products.

In addition, certain nutritional supplement products and Thai traditional drug products could be tampered with

sildenafil or tadalafil. Our study did not prove such tampering. However, based on data on the website of the Thai FDA³⁰, there were reports of products with such tampering that shared the product names with at least 14 products found in our study. This suggests that consumers could be harmed by the products found in our study.

Compliance with laws of label was found to be suboptimal. Among 42 nutritional supplement products with complete information on the label, label components with the least compliance were recommendation for storage (if any) (47.62%), month and year of manufacturing and expiration (69.05%), and warning “take all 5 food groups regularly with proper proportion” (73.81%). For 113 products that needed additional information from the texts on the website for evaluation, the least presented component was month and year of manufacturing and expiration (4.42%), followed by warning “no preventive or therapeutic benefit” (12.38%), recommendation on storage (if any) (13.27%), warning “not for children or pregnant women” (25.66%), warning “take all 5 food groups regularly with proper proportion” (26.54%), and components and their content amount (37.16%). Of these 155 products, 80.00% had components that needed no warnings while 20.00% did so. Of the 20 products, only 4 of them (20.00%) had the warning in place while 27 of them (87.10%) showed no or incomplete warnings. These findings indicate the need of more rigorous monitor for legal compliance on the product labels especially month and year of manufacturing and expiration. However, it is important to know realize that the incorrect or incomplete information of month and year of manufacturing and expiration does not directly cause harms to the consumer because the actual products bought by the consumer were different from the ones shown on the website. In addition, products that did not show warnings on the website may have the warning on the actual product.

Of the 31 products that contained components requiring specific warnings, 87.10% did not do so. Components with very low incidents found in our study included flower pollen extract “not for patients with flower pollen allergy”, lecithin “product contains phosphatidylcholine, lecithin ... (number) ... mg per capsule equivalent to phosphatidylcholine ... (number) ... mg,” and ginko biloba leaves extract “coagulation might be prolonged.” In addition to the mandatory warnings of these substances, other substances were found in our study including ginseng, Cordyceps extract, and fish oil which could also prolong coagulation and increase bleeding risk of

warfarin.¹⁵ It could be possible that with more products to be found beyond our study, more substances that could increase bleeding of warfarin but with no legal mandatory warnings could be expected. In terms of advertisement, all components were legally complied with suboptimal level. More attention on effective monitoring and control is needed.

Methodologically it is worth noting that the first product with non-redundant trade name was selected for evaluation. However, information of that selected product could be different from website to website. Therefore, not all components of the label and advertisement of the given product were evaluated. The products that were selected were those found in the websites listed early in the URL list. These selected websites could be an adequate representative of the product population since our searching method was considerably consistent with the searching behavior of the consumer. After fewer relevant products were found in later websites, consumers usually re-start their search with new keywords.

This study had certain limitations and drawbacks. First, nutritional supplement products with male sexual performance enhancement were defined as any nutritional supplement products with the content on the label indicating or implying the benefit of enhancing male sexual performance, maintaining penis erection, delaying ejaculation, but not those with only the benefit of arousing sexual desire, or enlarging penis size. Our finding could be different from the past reports and future studies.

Second, since product on websites had been changing all the time, re-verification of the data was done with less confidence. The researcher handled the problem by capturing the screen of the websites. For those websites not captured, the researcher re-searched the website with the same method. Disparity of the websites found from different searching could result in different findings.

Third, since some pictures of label on the product package did not provide adequate information for evaluation so the texts on the website were needed. The more sources of information were needed, the more chances of bias of different information selected from product to product.

Fourth, evaluation of the label based on the picture on the website could cause certain variations. Future studies could also use additional information from the actual product to confirm that from the website. Fifth, the use of Internet platform with the search engine GoogleTM, population of study

products could be limited. To cover more products seen by the wider public, more online platforms such as Facebook and Instagram should be included in future studies. Sixth, information obtained could be limited since the pictures shown on the website were mostly from the front of the product package. Information could be limited.

Seventh, not all types of products with male sexual performance enhancement were included in this study such as coffee. Future studies should include products with rising popularity. Eighth, since the first website with the trade name product was selected for evaluation, some information of the product which could be found in later websites could be missed. Different results could be found if more information from later websites was allowed. Ninth, since video clips on the website were not included in the evaluation, results could be different if allowed. More studies including video clips for evaluation should be conducted. Tenth, since the number of products included in the study was lower than the calculated sample size, representativeness of the sample could be lower than expected. Future studies should strive for adequate sample size which is high possible with the increasing number of these products on the Internet and social media platform.

For practical policy implications, it is recommended that regulatory agents such as the FDA should allocate more resources, both budget and personnel, for more systematic vigilance system on these products, rather than occasional operations in response to occasional complaints. With its easy operation, evaluation method in this study could be a prototype for future monitoring system and research. A comprehensive monitoring on products advertised on online platform could be done in an even more timely fashion before adversities could happen to the public. For education purpose, all stakeholders from the FDA to the provincial health administration office should have regular campaigns or programs to inform the public with more effective educational materials and communication channels and media. Certain education materials have been developed and distributed.³¹ More of these materials should be developed and distributed or communicated with the public with more effective strategies.

In conclusion, nutritional supplement products with male sexual performance enhancement claim on websites were found to be in a large proportion compared with drugs and cosmetic products. Compliance with the laws regarding label, warnings and advertisement was not perfect and need

improvement. More effective monitoring and education strategies are needed.

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