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Abstract	In order to contribute to further discussion of internet drug sales, we surveyed 3468 Pharmacy websites over the Internet in Japan. There were 279 sites (8.0%) having mail-order sale via the Internet. Almost all of them were selling health foods 213 (76.3%), then medicines 156 (55.9%), cosmetics 125 (44.8%) and elderly care products 37 (13.3%). Inside the medicines, there were 121 (77.6%) selling “Over The Counter” (OTC) drugs. We classified the OTC drugs by their mechanism of action; the most numerous were nutrients tonics and alteratives (85.1%), dermatological ointments (38.8%), digestive aids (38.0%), urological, reproductive, proctological (34.7%), gynecological medicines (33.1%) and cold medicines and related drugs (21.5%). We found a lot of sites vending medicines not allowed to sell over the internet, including 39 websites selling Group 1 classified OTC drugs prohibited to sell under the new legislation approved on 2007. This indicates the necessity of new methods to control this situation.
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Original Paper

The sale of over-the-counter (OTC) drugs over the internet in Japan

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In order to contribute to further discussion of internet drug sales, we surveyed 3468 Pharmacy websites over the Internet in Japan. There were 279 sites (8.0%) having mail-order sale via the Internet. Almost all of them were selling health foods 213 (76.3%), then medicines 156 (55.9%), cosmetics 125 (44.8%) and elderly care products 37 (13.3%). Inside the medicines, there were 121 (77.6%) selling "Over The Counter" (OTC) drugs. We classified the OTC drugs by their mechanism of action; the most numerous were nutrients tonics and alteratives (85.1%), dermatological ointments (38.8%), digestive aids (38.0%), urological, reproductive, proctological (34.7%), gynecological medicines (33.1%) and cold medicines and related drugs (21.5%). We found a lot of sites vending medicines not allowed to sell over the internet, including 39 websites selling Group 1 classified OTC drugs prohibited to sell under the new legislation approved on 2007. This indicates the necessity of new methods to control this situation.

Key words: Internet Pharmacy, Online Pharmacy, Over-the-Counter Drugs

INTRODUCTION

In 2001, we investigated the phenomena of internet sales through websites specializing in medications. These sites are called "Cyber Pharmacies", "Online Pharmacies" or "Internet Pharmacies". In this investigation we call them "Internet Pharmacies". We uncovered problems with this new sales method that requires no personal communication with a pharmacist; some websites illegally advertised and sold prescription-required medications and over-the-counter (OTC) drugs, and it was questionable whether some sites were in fact pharmacy websites.[1] Although control over unauthorized sales of medicine outside the scope of the Japanese Pharmaceutical Law system has become tighter, legal restrictions and measures to deal with internet sales of authorized medicines have remained the same since the current regulations notified in 1988[2]. To contribute to further discussion of internet drug sales, we investigated here the present condition of medical-supplies sales by websites clearly stated on the site to be a "pharmacy".

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METHODS

We selected and examined only websites indicating "mail-order sales" service among Japanese sites found by an internet search for those self-identified as "pharmacies" over the internet.We found 3,468 such websites listed on November 16th of 2005. We categorized the drugs that were listed on these sites by type of medication. For OTC drugs, we followed the classifications in the "List of OTC Drugs in Japan, 2004-5" and for those not listed, we followed the classifications presented on the Japan Self-Medication Industry (JSMI) website. We then classified these drugs following the 1988 notification that allows for internet drug sales. Following the

final "Risk Classification" released in March 2007 [3] by the Ministry of Health and Welfare Council of Revising Medication Sales, based on the Pharmaceutical Law amended in June 2006, we investigated actual conditions of possible illegal internet sales of Group 1 OTC drugs, which require in-person sales only.

RESULTS

1. Types of Items and Medicines

Among the 3,468 Internet Pharmacies examined, 279 offered mail-order sales (8.0%). Of the 279 internet pharmacy websites, health foods were handled by 213 (76.3%), medicines by 156 (55.9%), cosmetics by 125 (44.8%), and elderly care products by 37 (13.3%) (Fig.1). Among the websites handling medicines, OTC drugs were handled by 121 (77.6%), Chinese herbal medicines by 102 (65.4%), pharmacy-manufactured preparations by 6 (3.8%), and prescription medicines by 3 (1.9%) (Fig.2). For OTC drugs, the most frequently handled type of medicine, we divided these into sub-categories by specific purpose, and present the data in Fig.3. The most frequently handled medicines by websites were nutrients tonics and alteratives, such as virility enhancers (85.1%), followed by dermatological ointments such as antiseptics or scabies treatment (38.8%), digestive aids (38.0%), medicine containing androgen for urological, reproductive, and proctological use (34.7%), gynecological medicines such as for irregular menstruation (33.1%), and cold medicines and related drugs (21.5%).

2. Websites Violating the Current Regulations (Notified in 1988) and Violating the Risk Classification

Among the OTC drugs sold online, there are some groups of medicines that are not listed in the current regulations published in 1988. Other groups of medicines are listed but contain prohibited ingredients. The types of medicines that are not allowed to be sold through the internet are related to smoking control, for use in medical tests, otolaryngological medicine, allergy medicine, gynecological medicine,

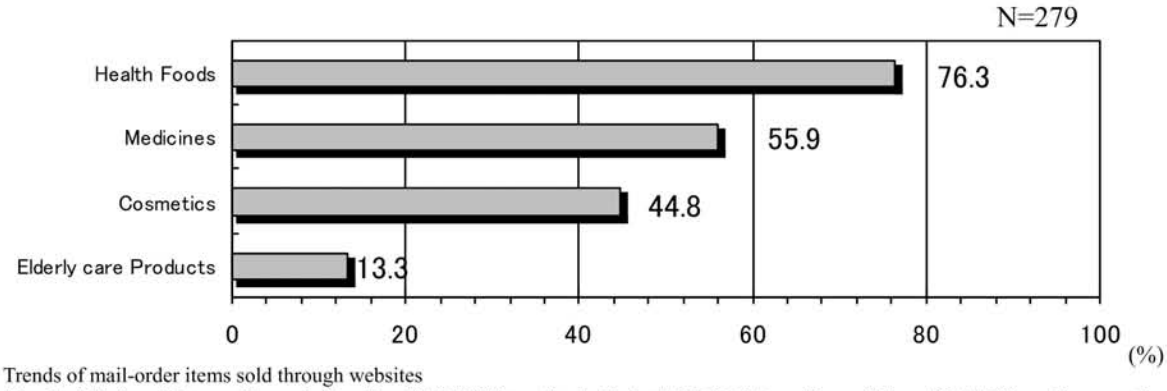

Fig.1 Trends of mail-order items sold through websites
Examining the 279 sites of "Internet Pharmacies" we found 213 (76.3%) vending health foods,156 (55.9%) vending medicines, 125 (44.8%) vending cosmetics and 37 (13.3%) vending elderly care products.

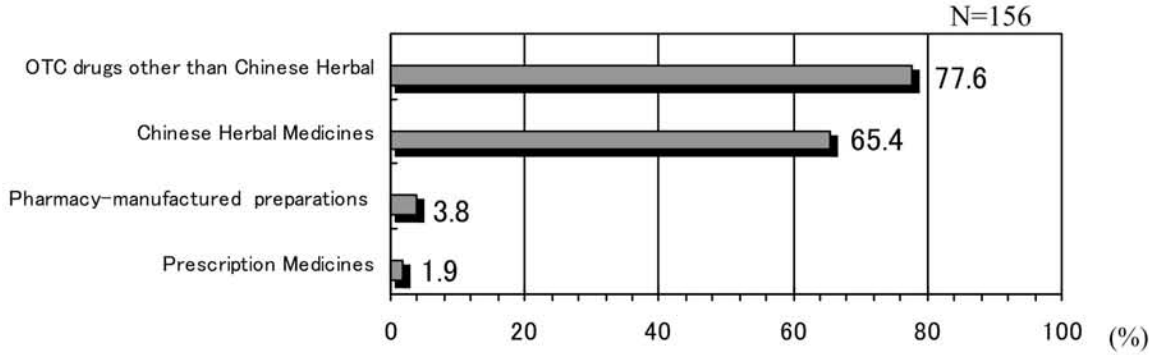

Fig.2 Types of medicines sold through websites
Inside the "Internet Pharmacies" vending Medicines,121 (77.6%) handled OTC drugs,102 (65.4%) handled Chinese herbal medicines,6 (3.8%) handled Pharmacy-manufactured preparations and 3 (1.9%) handled Prescription medicines

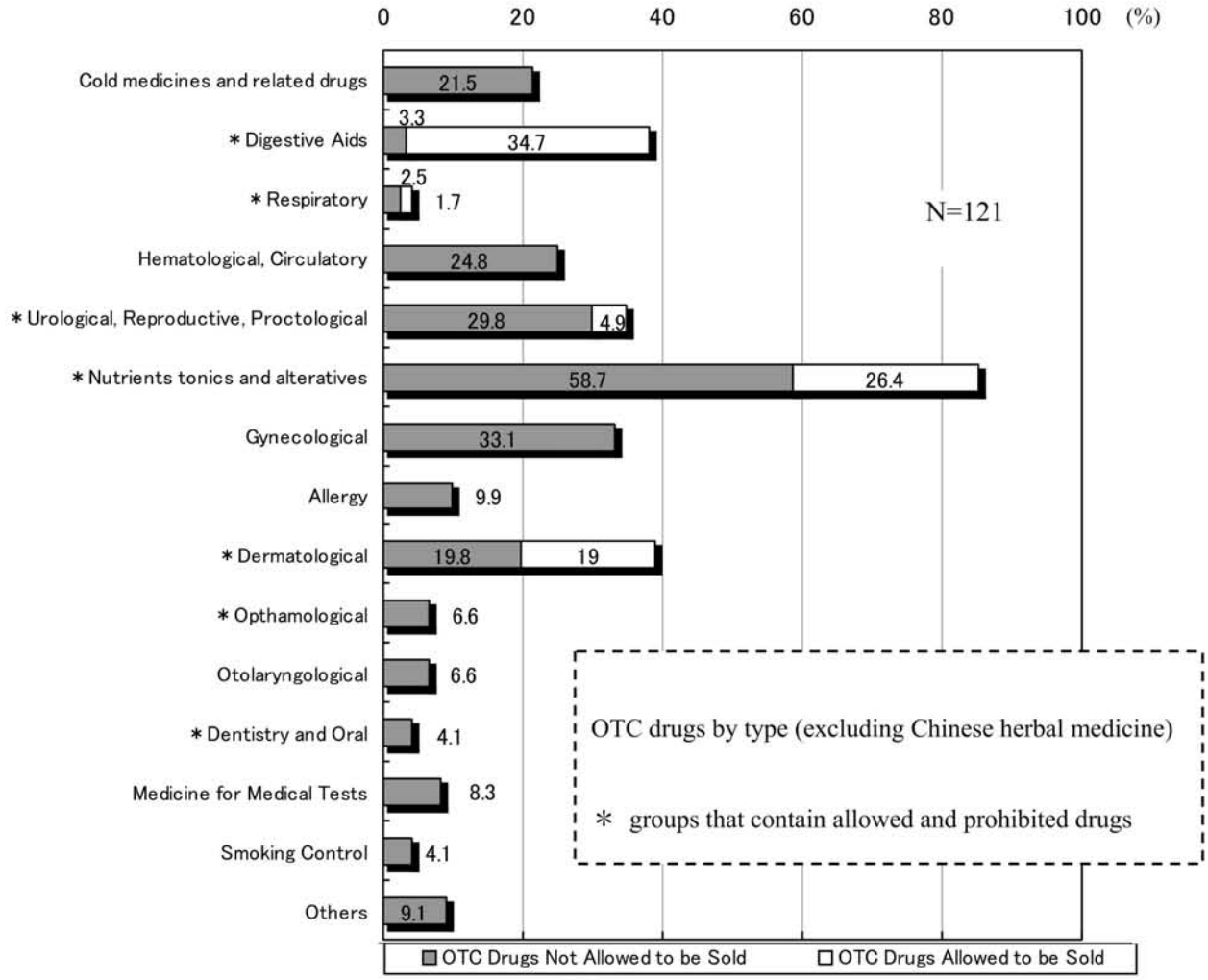

Fig.3 Comparison of OTC drugs classified by medicinal action
At the 121 Internet Pharmacies vending OTC drugs, almost all the sites were vending medicines not allowed to sell over the internet.

circulatory medicinez, hematological medicine, cold medicines and related medicines, and others, as listed in Fig.3. The types of medicines that are listed but contain prohibited ingredients are indicated by an asterisk. As can be seen from Fig.3, there is a remarkable variety of unauthorized medicines sold online.

In spite of the "Risk Classification" released in March 2007, we found 39 (32.2%) websites handling Group 1 medicines: 31 handled urological, reproductive organ, and proctological medicine (containing testosterone, methyltestosterone, yohimbine hydrochloride and strychnine nitrate); 20 handled dermatological medicine (containing terbinafine hydrochloride, minoxidil and testosterone); 11 handled nutrients tonics and alteratives (containing methyltestosterone); 4 handled digestive aids (containing cimetidine, ranitidine, famotidine and roxatidine acetate hydrochloride); 2 handled otolaryngological medicine (containing Ketotifen fumarate); 2 handled respiratory medicine (containing theophylline); and 1 handled cold medicines and related drugs (containing theophylline) (Fig. 4).

DISCUSSION

1. The increase in internet users in Japan

The number of internet users has increased rapidly in recent years, following the progress of IT technology[4] At February of 2006, the prevalence of internet users in Japan was 57.3%. Results of an interactive survey of teenagers of both genders who use the internet at home show that 89.9 % have experienced online shopping[5], and that 27.5% have purchased medicines or health food online.[6] Today, using personal computers, it is entirely possible for internet users to buy medicine from all over the

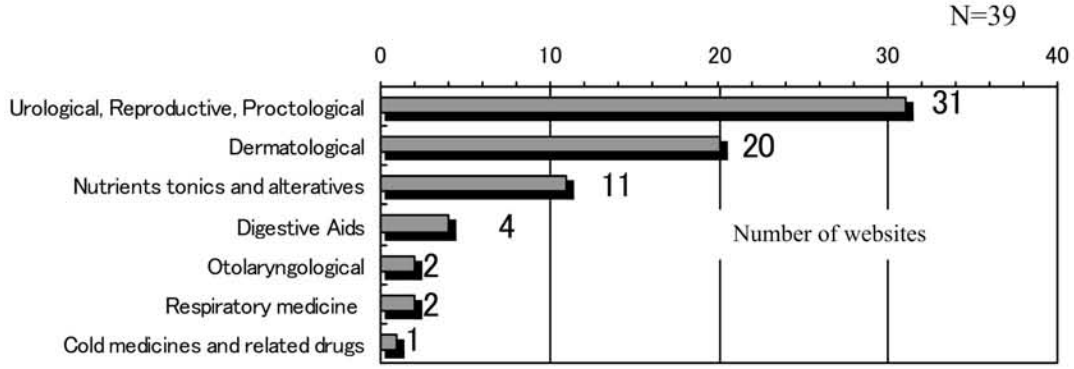

Fig. 4 Websites selling Group I classified medicines (Risk Classification)
Into the 39 Internet Pharmacies vending OTC drugs classified as Group 1 of the Risk Classification,

world as easily as buying music CDs and books.

2. The Phenomenon of OTC Drug Sales in Japan

The variety of medicines handled by websites was wide; from 1 to 1300 types of medicines on any one site. A number of websites had homepages with confusing layouts, which made it difficult to distinguish medicines from health food products. However, the planned requirement for label indication of OTC drugs following enactment of the "Risk Classification" law should in future make it possible to distinguish medicine clearly from health food. Under the current 1988 regulations, internet sales of medicine are regarded as "mail order" sales. Therefore, decisions made concerning which medicines can be sold online are based only on the list of medicines that appeared in the 1988 regulations. This regulation was issued as only a notice and has no penalty clause. Consequently, many websites ignore it and continue sales of unauthorized medicine. Some medicines such as virility enhancers and scabies treatment that are somewhat embarrassing to purchase in person are frequently and conveniently sold through internet pharmacy websites. This study examined websites from all over Japan that self-identified as pharmacies, and we found them operating from all Japanese prefectures. While we did not check every website identified, if these pharmacies are in fact all legally authorized, they comprise 6.9% of the total 50,600 Japanese pharmacies registered in 2004. In our previous work we found that there were some internet pharmacies without detailed addresses, or with incorrect addresses, which revealed the obscure nature of internet sales.[1)] In this study we found that 279 of the 3,468 (8.0%) websites that self-identified as pharmacies on an internet search had internet pharmacy sales, and 156 (4.5%) of them handled medicines. These percentages are still relatively low but they are likely to increase given global trends and recent Japanese drifts toward deregulation. We believe it is important to understand the circumstances of internet pharmacy sales with the aim of considering further regulatory measures.

3. The Future of Internet Pharmacies in Japan

Theoretically, in-person sales should be the default preference for pharmacy-related items, and it is even more desirable for sales of medicine. However, given the many convenient aspects of internet sales, this mode of shopping cannot be ignored for long. In order to help guarantee consumer safety, some surveillance system to manage websites handling medicine should be implemented. Even if all internet pharmacy sales were to become prohibited by regulation, it would be almost impossible to have a system capable of confirming compliance. Therefore, more realistic responses such as implementing an "Internet Version of Standard Pharmacies" should be considered so that consumers would have a means through which to find and distinguish reliable and compliant websites from among the more evasive ones operating. Some low-cost third-party evaluation system should be introduced to approve only those pharmacies who meet the standards. Alternatively, perhaps a means could be devised to guarantee that registered pharmacies are listed and easily distinguished online so that general users will have a clear reference to consult.

The medicines focused on in this study are OTC drugs. Detailed study of prescription medicine sales is also necessary to further understand the issues.

Under the current National Health Insurance systems most Japanese citizens find prescription medicine more reasonably priced than their internet counterparts, so there are only limited advantages to internet medicine sales from a financial standpoint. However, if the cost of internet medicine drops below regular prescription prices-as often occurs in the United States- internet sales will likely expand. Some organizations, such as the Japan Pharmaceutical Association, should consider immediate preparations to cope with this possible future scenario. If a website self-identifies as a "pharmacy," it must be distinguished from individual importers and provide proper comprehensive services as a "site where pharmacists are stationed."

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