



IJPPR

INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals

ISSN 2349-7203





Human Journals

Short Communication

June 2019 Vol.:15, Issue:3

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Study on Drug Classification and Relevant Professional Qualifications in Japan

			
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Submission:	23 May 2019		
Accepted:	29 May 2019		
Published:	30 June 2019		



www.ijppr.humanjournals.com

Keywords: Drug classification, professional qualification, registered sales clerk, role of pharmacists.

ABSTRACT

Drugs (medicines or pharmaceuticals) are government-approved products used for treating diseases and injuries. Usage of drugs leads to not only effects but also side effects; therefore, drugs are not allowed to be sold and purchased everywhere. In Japan, the act concerning pharmaceuticals (Pharmaceutical Affairs Law) was revised in 2009, and as a result, classification of drugs became complicated. Nevertheless, it became possible to obtain drugs that have less effects and side effects even with less professional involvement. Simultaneously, a new qualification called registered sales clerk has been introduced. These revisions can be considered deregulation in that the number of ways for obtaining drugs has increased, and it has become easier to buy and deliver drugs. The present article focuses on the current issues associated with purchasing drugs in Japan, in particular, those related to drug classification and relevant professional qualifications. We believe that the current drug marketing methods or the presence of professionals have both advantages and disadvantages. In particular, we believe that it may be necessary to make further changes pertaining to safe use of drugs.

INTRODUCTION

Drugs (medicines or pharmaceuticals) are products intended for the treatment of diseases and injuries. In Japan, the effects of the active ingredients in drugs were identified by the Ministry of Health, Labor and Welfare (MHLW). There is a big difference from foods including healthy foods in that certain effects are observed for the disease and the country doesn't guarantee it. Usage of drugs is also characterized by side effects in addition to the effect of curing the disease. In other words, drugs are not usually consumed as food, but are products used in case of disease taking their effects and side effects into consideration. At present, in Japan, drugs, quasi-drugs, and cosmetics as internal and external preparations are used for health maintenance and disease treatment. Among these, drugs can be classified in several ways, for example, drugs that require a doctor's prescription and over-the-counter (OTC) drugs that can be easily purchased at drug stores. In addition, there are several differences, such as types of professionals who can be associated with sales and consultation, accountability to customers, and sales methods.

In recent years, laws in Japan have been amended, and many points regarding the handling of drugs are changing. The means of marketing drugs have changed, and classification of general drugs has been introduced. In addition, a registered sales clerk was recently established as a type of professional qualification. The provision of registered sales clerks gives patients the advantage of being able to easily obtain drugs without visiting medical professionals or a drug store. However, a drawback is that general consumers are made to feel the kind of drug complex and it is difficult to make an optimal choice. Therefore, this paper gives an overview of the classification of drugs and the relevant professional qualifications in Japan and describes the author's thoughts on its advantages and disadvantages.

Classification of products that are effective for diseases

An outline of the classification of products that are effective for diseases is presented in Table 1. Apart from drugs, quasi-drugs and cosmetics are considered to have certain effects on health. Effects of quasi-drugs are similar to those of drugs. Quasi-drugs are approved by the MHLW, and contain ingredients that are effective for diseases at a certain concentration. Although quasi-drugs may be considered weak, they exhibit certain effects. Quasi-drugs are products that are often used to maintain health in terms of disease prevention and hygiene, rather than disease treatment. What is displayed as "medicinal" corresponds? Certain

products that were recognized as drugs in the past have been recently recognized as quasi-drugs because they have few side effects. They are similar to drugs and are different from products such as health foods¹⁾. Health foods do not have an obvious effect on many people and are usually considered to have only mild effects such as assisting the primary treatment or enhancing the effect of drugs. Cosmetic products are also products that have been approved for efficacy; however, they have a milder efficacy than quasi-drugs. It is difficult to compare cosmetics with health foods in terms of the strength of the effects. In Japan, drugs, quasi-drugs, and cosmetics are defined in the Pharmaceutical Affairs Law. Although these three products differ in their strength of action, they can be considered as products whose effects on treatment of diseases is guaranteed by the country.

Drug classification

Although Table 1 presents one type of drug classification, several other drug classifications exist²⁾. With the 2009 revision of the Pharmaceutical Affairs Law, the current classification has been introduced, according to which drugs are divided into the following three categories: 1) drugs that can be received by the pharmacy department of a hospital or an ethical pharmacy based on a prescription (medicinal drugs), 2) drugs that can be purchased at a local pharmacy (OTC drugs), and 3) drugs that can be bought online. Outside of Japan (for example, the United States), all OTC drugs that do not require prescriptions can be purchased at retail stores³⁾. In the text, the drugs listed earlier (above in Table 1) can be considered as products that are more effective but have more side effects. With regard to measures to be taken when no effect is observed or side effects occur, it is possible to take medication after receiving information from a medical professional. Drugs that can be purchased by mail order have very few side effects for a long period, and for these products, professional explanations are provided by telephone and email at the time of purchase and delivery (in addition, consultations can be received by telephone or email). However, it would be inaccurate to assume that side effects do not occur; therefore, it is required that users follow the recommended usage and doses in detail according to the accompanying text. The same applies to the categories 1 to 3 of the OTC drugs shown in Table 1, and it can be considered that class 1 drugs are the most effective, and side effects are likely to occur. Therefore, a written description of side effects and other information by a pharmacist is obligatory. If face-to-face contact is difficult during the sale of class 1 drugs, the instructions will be offered through other means such as email. Patient information such as age, sex, allergies, and

medical history will be confirmed by asking by the PC chat or over the telephone. In contrast, in the case of class 2 drugs, the explanation is duty of effort, and in the case of class 3 drugs, an explanation is not mandatory. As more than 95% of OTC drugs are designated as class 2 or 3 drugs, such drugs with only moderate effects can be purchased without contacting a pharmacist. This can be considered as part of deregulation. Consumers are less likely to buy drugs on the basis of only word of mouth by acquaintances⁴⁾. However, drugs are often purchased by referring to the effects described on the package and information provided by TV commercials⁵⁾.

Types of medical professionals

As already mentioned in the previous section, qualified professionals who can provide drugs include pharmacists who are professionals concerned with dispensing drugs, in addition to doctors and dentists who are mainly engaged in the treatment itself. In addition, since 2009, the qualification registered sales clerk has been new. Doctors, dentists, and pharmacists can obtain a license (national qualification) by passing a national exam after taking prescribed subjects at a specialized six-year school. Registered sales clerks can obtain a license (national qualification) by passing examinations established by prefectures and two years of work experience. When prescribing a drug based on a prescription from a hospital, the prescribing doctor or dentist or the dispensing pharmacist will be responsible for providing information on the drug. In contrast, pharmacists or registered sales clerks will be responsible for selling and receiving drugs purchased at local pharmacies, depending on their classification. For other products, manufacturers and sellers will be responsible to a certain extent, and they will be consulted by a professional (mainly a pharmacist) over the telephone. In other words, a place to consult professionals or report complaints to professionals in a familiar setting is unavailable. In particular, there have been several reports of side effects caused by taking the prescribed dose and those due to taking more than the prescribed dose in an attempt to increase the effect. Although the latter situation cannot be completely avoided by providing professional explanation, it is regarded as a problem that such a situation may occur owing to a lack of professional explanation. This can be viewed as a drawback of deregulation of drug sales. The medical doctor training course is a 6-year system as before; however, since 2006, the pharmacist training course was changed from a 4-year system to a 6-year system. During the additional period, the training pharmacists have various practical experiences in dispensing pharmacies and hospitals. In contrast, because a registered sales clerk's license is

easy to obtain, it can be obtained even without sufficient knowledge and experience, which leads to problems in the actual work settings. In this regard, it may be necessary to properly verify the work experience and make it a prerequisite for the qualification.

CONCLUSION

The revision of the Pharmaceutical Affairs Law in 2009 made it easier to purchase drugs that are less effective. It is also true that the emergence of registered sales clerks has increased the number of drugs that can be purchased without a pharmacist. We believe that these have both advantages and disadvantages. Drugs are used primarily for the purpose of treating diseases, but there are also risks (side effects). Depending on the situation, it is necessary to use another drug to suppress the side effects or to select a drug that matches the patient's constitution. Doctors and pharmacists are the ones who have to take responsibility as professionals for their selection. It is believed that medications consumed by patients aid in healing and are less likely to cause side effects only if the patients take the appropriate dose of the appropriate type of medication. Considering this, patients being able to easily obtain drugs without contacting professionals are not always a good idea. Doctors, dentists, and pharmacists can choose the most appropriate drug from all drugs. In familiar places such as towns, receiving an explanation from a pharmacist seems to be extremely important for selecting an appropriate drug. Such procedures may seem inconvenient to the general consumers, but they likely lead to better results than continuing to take less effective medications that fail to improve the patients' symptoms. Judging the patients' symptoms in an emergency, it is not known whether general consumers can select appropriate drugs. It is necessary to consider whether the drugs that are easily available are sufficient for emergency use. The practice of receiving drugs by mail order also lacks in credibility. Consumers select and purchase drugs by consulting a professional by email or telephone, but the professional is a pharmacist working for a pharmacy, hospital, or pharmaceutical company. Often, all candidate products are not presented from the beginning. Of course, consultations are being conducted as a job. There may be an inventory of drugs that the pharmacist wants to sell. It is difficult to predict whether fairness will be properly maintained and a truly optimal drug will be selected. Can a consumer who is obliged to go to a pharmacy to receive an explanation properly confirm the necessary information at the time of mail order? According to a previous report, during OTC drug purchase, many consumers tend to make a decision with an emphasis on convenience⁶⁾. Under such circumstances, is it possible to make an appropriate

selection? From a scientific perspective, there is uncertainty about the effectiveness of OTC drugs. In particular, the concentration and ratio of the combination agent remain unknown⁷⁾. This is strongly linked to the risk of side effects even with OTC drugs.

Drugs are not consumed as food; their usage also involves risks. Consumers tend to emphasize only the benefits of the current system, that is, the ease of obtaining drugs. Registered sales clerks, as professionals, also need to have knowledge of drugs that they cannot sell and should not supply drugs that are not appropriate. In our opinion, it may be necessary in the future to simplify drug classification and reexamine marketing methods (stopping deregulation).

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Table 1: Classification of drugs and similar products

Type	Subdivision	Professionals who respond	Description from seller to customer	Responding to customer consultation	Sales via the Internet, postal mail, etc.	Outline
Drugs	Medicinal	Doctor, dentist, pharmacist				Drugs that a doctor prescribes according to the patient's disease, symptoms, and constitution and a pharmacist dispenses based on the prescription.
	O T C	Require d Medical Supplies	Providing information face to face (obligatory)	Obligatory*	Not possible	Drugs that were previously categorized as medicinal drugs and are currently categorized as OTC drugs. The risks such as side effects are indeterminate; therefore, they cannot be bought without receiving an explanation from the pharmacist.
		Non-prescription	Class 1	Providing information in writing (obligatory)		Possible

			Class 2	Pharmacist or registered sales clerk	Duty of effort				with other drugs.
			Class 3						Taking safety precautions against side effects and concomitant use with other drugs is necessary.
Quasi-drugs					No legal provisions				Active ingredients are blended at a certain concentration. The effect is weaker than that of drugs. MHLW-approved products.
Cosmetics			Not required			Not required			Less effective than quasi-drugs. Products used for the purpose of cleansing, beautifying, increasing attractiveness, and keeping healthy.