Japan Research Institute
JRI Research Journal
https://www.jri.co.jp/en

Vol.8 No.1
January 9, 2025

OTC-like Drugs Should be Classified as OTC Drugs

— It is essential to return from medical drugs to the starting point of prescription drugs —

Michinori Naruse*
naruse.michinori@jri.co.jp

〈Summary〉

◆ This paper focuses on the issue of OTC-like drugs, which are key to curbing the cost of public medical insurance benefits. Drugs are broadly categorized into those that require a doctor's prescription and those that do not, namely OTC drugs (over-the-counter drugs). The need for a prescription should be determined on the basis of risk, and in fact, in various countries, governments classify high-risk drugs as drugs that require a prescription, and low-risk drugs as OTC drugs. The term OTC-like drug is used to mean a drug that is similar in nature to an OTC drug in terms of factors such as effect and risk, but that normally requires a prescription.

◆ The product group called OTC-like drugs has arisen because the standard for determining the need for prescriptions in Japan is actually a double standard, with one standard for prescription drugs and another for medical drugs, and because medical drugs have become the main focus despite not originally being the target of the standards. Whether a drug is a prescription drug is determined by the level of risk, and only high-risk drugs are classified as prescription drugs, and a prescription is required to purchase them. However, even low-risk drugs that are not classified as prescription drugs are not automatically made available without a prescription in Japan, and if one has been classified as a medical drug pursuant to an application by the manufacturer, a prescription is normally required to purchase it, and it is covered by public medical insurance. In Japan at present, drugs other than medical drugs are considered to be OTC drugs.

◆ There are four main problems with drugs that are similar in nature to OTC drugs being

* Senior Economist (Economics Department, JRI).

covered by public medical insurance and normally requiring a prescription. The first is that they impede self-medication. Patients who visit a medical institution (hospital or clinic) and are prescribed OTC-like drugs pay less out of pocket for drugs than if they purchased OTC drugs directly from a pharmacy. In other words, self-medication is more expensive. The second stems from the first, and is that it puts pressure on medical insurance finances. According to estimates prepared for this paper, OTC-like drugs account for 2.3%, or 1.0 trillion yen, of the 45 trillion yen in national medical expenditure (FY2021). The third is that it undermines the fairness of the health insurance system. A system whereby health insurance covers the drug costs of those who immediately go to a medical institution and are prescribed OTC-like drugs even if they only have mild symptoms cannot be described as fair. The fourth is that it makes it difficult for patients to purchase OTC-like drugs directly at pharmacies, which can be seen as a disadvantage for patients. Above all, many OTC-like drugs are more cost-effective than OTC drugs.

- In light of the above, the classification of medical drugs should be abolished and drugs other than prescription drugs should be classified as OTC drugs. This could be expected to solve the above-mentioned problems. However, concerns could also be expected to arise, such as higher drug costs due to doctors prescribing substitutes that are covered by public medical insurance benefits, poorer access to drugs for patients due to increased out-of-pocket payments, and improper use due to reduced physician involvement. These concerns can be addressed through, for example, monitoring and guidance for doctor's prescriptions, the provision of exceptional insurance benefits in the case of serious illnesses, and ensuring that pharmacists provide thorough guidance to patients.

- **This is a English version of "OTC 類似薬は OTC 医薬品に区分を－本質は医療用医薬品から処方箋医薬品への原点回帰－" in JRI Review (The original version is available at https://www.jri.co.jp/MediaLibrary/file/report/jrireview/pdf/15395.pdf)**

1. Introduction

National medical expenditure has now reached 45 trillion yen (FY2021), and the increase in the burden of medical insurance premiums and public expenses (taxes and government bonds) has depressed the disposable incomes of the current generation, and also become a major factor in Japan's fiscal deterioration. Curbing the cost of public medical insurance benefits has been a perennial issue, but it has become even more critical recently. As a means of financing childcare support measures, the government has established a system for collecting one trillion yen per year to fund child/childcare support by adding it to medical insurance premiums, while explaining that aggressive spending reforms will mean that the public incurs no real additional burden. However, there are question marks over what exactly these spending reforms will entail. Furthermore, with Japan's public finances saddled with a huge amount of debt, rising interest rates are expected to result in a significant increase in interest expenses, so fiscal reconstruction is no longer something that can be postponed. This paper focuses on the issue of OTC (over-the-counter)-like drugs, which are key to curbing the cost of public medical insurance benefits.

The term OTC-like drug is used to mean a drug that is similar in nature to an OTC drug in terms of factors such as effect and risk, but that normally requires a prescription. OTC drugs are drugs that can be purchased directly without a doctor's prescription at pharmacies and drugstores, and include cold medicines, gastrointestinal medicines, vitamins, gargles, compresses, eye drops, and herbal remedies. OTC-like drugs are covered by public medical insurance (with 10% to 30% paid out of pocket), while OTC drugs are not covered (the full amount is paid out of pocket). Note that the criticism in this paper is directed at the institutional treatment of products called OTC-like drugs, not the products themselves. Despite the negative connotations of "-like," the products should be regarded as valuable.

In this way, drugs that are similar in nature to OTC drugs are covered by public medical insurance and normally require a prescription, which places a heavy burden on medical insurance finances but is advantageous for patients. According to estimates prepared for this paper, OTC-like drugs account for 2.3%, or 1.0 trillion yen, of the 45 trillion yen in national medical expenditure. Furthermore, patients who need OTC-like drugs need to go to a medical institution to get a doctor's prescription, and that also costs money. OTC-like drugs tend to be more cost-effective than OTC drugs, and the fact that OTC-like drugs cannot be purchased directly at pharmacies can be said to be a disadvantage for patients.

Therefore, this paper, after providing some background information on OTC-like drugs, explores the problems related to them, and considers solutions. The structure of this paper is as follows: Chapter 2, which follows, points out the problems with the current situation after providing basic information such as the institutional factors that caused the product group called OTC-like drugs to arise as well as the size of the markets and the characteristics of the products. Chapter 3 examines the background to the current situation, such as the historical lead-up and the calculations of industry stakeholders. Based on the preceding discussion, Chapter 4 proposes policies that should be adopted, and considers possible criticisms and ways of addressing them.

2. Current situation and problems with OTC-like drugs

(1) What are OTC-like drugs?

A summary of the product group called OTC-like drugs, the institutional factors that caused it to arise, and estimates of the size of the market are presented below:

Although the expression "OTC-like drug" is in common use, it is not a legally defined term. Nevertheless, the criteria for a drug to be considered an OTC-like drug can probably be narrowed down to the following two: 1) It is classified as a medical drug, and 2) it is similar in nature to an OTC drug in terms of factors such as effect and risk. In Japan at present, it is said that from an institutional point of view, drugs are broadly divided into medical drugs and OTC drugs. The sizes of the domestic markets for each are 11.1 trillion yen and 0.8 trillion yen, respectively (based on 2022 manufacturer shipments from the Ministry of Health, Labour and Welfare's Statistics of Production by Pharmaceutical Industry). A prescription is normally required to purchase medical drugs, and they are covered by public medical insurance.

Although criterion 1) is clear, regarding 2), there is no standard for how similar the drug needs to be called an OTC-like drug, so the scope of the drugs considered to be OTC-like drugs varies depending on who is discussing them. Similarity is often determined based on one of (i) active ingredient, (ii) efficacy, and (iii) risk. With (i), the idea is that an OTC-like drug is a medical drug with the same type of active ingredient as an OTC drug. For example, the active ingredient of both the OTC drug "Gaster10" and the medical drug "Gaster," which are gastrointestinal medicines, is famotidine, so the medical drug Gaster would be considered to be an OTC-like drug. In modern pharmaceutics, the active ingredient is regarded as the most important factor in determining the drug's effect and risk. With (ii), the idea is that OTC-like drugs are medical drugs with the same efficacy as many popular OTC drugs, such as cold medicines, gastrointestinal medicines, vitamins, gargles, and compresses. "Efficacy" is a term that expresses the purpose of the drug, i.e., what it is effective for, and does not encompass quantitative concepts such as how strong or mild the effect is. And with (iii), the idea is that OTC-like drugs are low-risk medical drugs. Whichever of (i)-(iii) is applied, there is a lot of overlap in the scope of drugs considered to be OTC-like drugs, but given the following institutional factors, the discussion in this paper will proceed based on (iii).

The product group called OTC-like drugs has arisen because the standard for determining the need for prescriptions in Japan is actually a double standard, with one standard for prescription drugs and another for medical drugs, and because medical drugs have become the main focus.

Prescription drugs are drugs that are required by law (Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices; below, "Pharmaceuticals and Medical Devices Act") to be prescribed by a doctor before they can be provided to a patient, and high-risk drugs are classified as such. The government categorizes risks as A-C below, and explains that if any one of them applies to a drug, it will be a prescription drug (Figure 1):

A. Likely to result in resistant bacteria or is difficult to use

B. Danger of serious side effects

C. Has a stimulant effect and is addictive

Figure 1. Designation Standards for Prescription Drugs

Designation Standards	Examples
Based on the doctor's diagnosis, possible courses of treatment have been considered, and for reasons such as resistant bacteria being likely to emerge or the drug being difficult to use, it cannot be used safely and effectively unless it is appropriately selected according to the patient's condition, constitution, etc.	Antibiotics Hormones All Injectable Drugs Narcotics
There is a risk of serious side effects etc., and to prevent their occurrence, it is necessary to understand the patient's condition by, for example, conducting regular medical examinations	Hypoglycemic Agents Antineoplastic Agents Blood Products
Due to the combination of stimulant effects, risk of dependency, etc., there is a danger of it being used for purposes other than the original intended use	Psychotropic Drugs

Source: Prepared by JRI based on Ministry of Health, Labour and Welfare, "Matters Related to the Revised Pharmaceuticals Affairs Act (Effective April 2005): Designation of Prescription Drugs," February 10, 2005, Pharmaceutical and Food Safety Bureau Director-General Notification No. 0210001

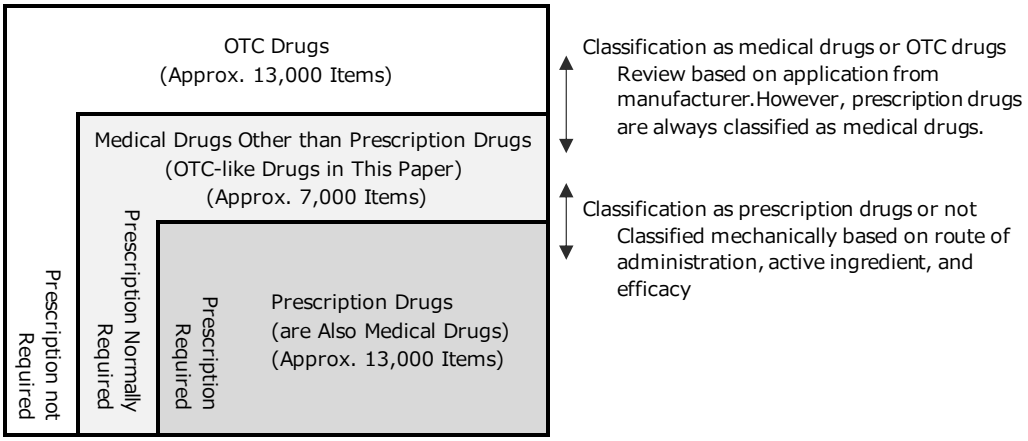
Which of A, B, or C a drug falls under is determined based on 1) route of administration (the route by which the drug enters the body), 2) type of active ingredient, and 3) efficacy. There are three 1) routes of administration: injectable drugs, internal (oral) drugs, and external drugs. All injectable drugs are categorized as falling under A, and are classified as prescription drugs. The classification of internal and external drugs is not determined by the route of administration, and strictly speaking, the decision on which of A, B, or C drugs fall under is made for each combination of 2) type of active ingredient and 3) efficacy (e.g., active ingredient: famotidine + efficacy: gastrointestinal medicine). In most cases, however, drugs with the same 2) type of active ingredient have the same 3) efficacy, and even government materials often use simplified expressions, stating that the decision to classify a drug as a prescription drug is made based on the active ingredient. If two drugs match all of 1)-3), they will always be assigned the same classification, with no consideration given to the manufacturer's wishes.

Incidentally, regarding the active ingredient, the effect and risk of the drug is proportional to the amount contained, but the decision on whether it will be a prescription drug is made based only on the type, with the amount contained not taken into account. The likely rationale for this is as follows: Whatever the type of active ingredient, harm can occur if it is taken in large quantities, and drug development rarely results in an amount contained that far exceeds the amount required to achieve a sufficient effect. Active ingredients where the amount at which an effect can be obtained (therapeutic range) and the amount that causes serious harm (toxicity range) overlap or are close to each other are judged to be high risk in the first place, and drugs containing them are classified as prescription drugs regardless of the amount they contain. On the other hand, in the case of an active ingredient where the therapeutic range and the toxicity range are sufficiently far apart, the risk is low regardless of the amounts of the active ingredient within the therapeutic range.

Conversely, regarding whether a drug will be a medical drug or an OTC drug, its classification is determined following a review based on the application from the manufacturer and after approval by the government. High-

risk drugs (drugs classified as prescription drugs) will not be approved as OTC drugs, so naturally, manufacturers will also apply for them to be designated as medical drugs. Meanwhile, low-risk drugs (drugs classified as other than prescription drugs) can gain approval as both medical drugs or OTC drugs based on the manufacturer's application (Figure 2).

Figure 2. Drug Classifications



Source: Prepared by JRI based on Ministry of Health, Labour and Welfare, "Sale of Medical Drugs Other Than Prescription Drugs" (Material for 1st Meeting of the Study Group on the Distribution System for Drugs, February 22, 2023)

By all rights, one standard, i.e., whether the drug is a prescription drug, should be enough, and in other countries it is the norm for the government to classify high-risk drugs as drugs that require a prescription, and low-risk drugs as OTC drugs, with the risk level determined based on factors such as the route of administration and the active ingredient. However, as explained above, in Japan, the main standard is whether a drug is a medical drug or not. The current situation in Japan is akin to a lodger behaving as though they were the landlord. Whether a drug becomes a medical drug can be affected not only by the risk level but also by the manufacturer's wishes. If it becomes a medical drug, there are advantages, as it is covered by public medical insurance. This reduces the burden on patients and allows the manufacturer to increase trust in the drug by emphasizing that it is for medical use. Such motives are in a different dimension from the issue of drug risk. Therefore, what could be described as a "medical drug bubble" was bound to occur. That bubble has ended up as OTC-like drugs. As mentioned above, the discussion in this paper will proceed with low-risk medical drugs, i.e., "medical drugs other than prescription drugs," defined as OTC-like drugs.

OTC-like drugs account for about 7,000 of the approximately 20,000 medical drugs. Although prescriptions are not required for OTC-like drugs under the Pharmaceuticals and Medical Devices Act, the Ministry of Health, Labour and Welfare (MHLW) has issued a notice that unless there are unavoidable circumstances, they should be sold based on prescriptions. Most pharmacies respect this, and the majority of OTC-like drugs are sold on a prescription basis.

The size of the market for OTC-like drugs in FY2021 was estimated, from NDB Open Data, to be 1.0 trillion yen (Figure 3). Due to the nature of the raw data, only data for the top 100 drugs in terms of the number of prescriptions for each efficacy was released, so this figure is likely to be a slight underestimate. By route of administration, as mentioned above, all injectable drugs are prescription drugs, and OTC-like drugs are internal

drugs (700 billion yen) or external drugs (300 billion yen). As for efficacy, in the case of OTC-like drugs, amounts sold are particularly large for herbal/crude drugs, drugs for digestive organs (gastrointestinal medicines etc.), epidermal drugs (compresses etc.), and allergy drugs (Figure 4). As far as internal and external drugs are concerned, in the case of herbal/crude drugs, cough suppressants and expectorants, hemorrhoid medicines, and gargles, all medical drugs are OTC-like drugs. On the other hand, drugs for serious diseases, such as anti-cancer drugs, are usually classified as prescription drugs, so hardly any of them are included in OTC-like drugs. And drugs for lifestyle diseases such as hypertension, diabetes, hyperlipidemia, and gout, for which the markets are large, are also classified as prescription drugs, with only a few exceptions, such as those with the same active ingredients as health foods.

Figure 3. Amount Sold of Medical Drugs by Route of Administration and Classification (FY2021)

(100 million yen)

Route of Administration	Medical Drugs Other than Prescription Drugs (OTC-like Drugs)	Prescription Drugs	Total
Internal Drugs	7,194	42,252	49,446
External Drugs	3,258	4,567	7,825
Injectable Drugs	0	31,391	31,391
Total	10,452	78,210	88,662

Source: Prepared by JRI based on Ministry of Health, Labour and Welfare, "8th NDB Open Data"

Figure 4. Amount Sold of Internal and External Drugs by Efficacy and Classification (FY2021)

Efficacy	Medical Drugs Other than Prescription Drugs (A) (OTC-like Drugs) (100 million yen)	Medical Drugs (B) (100 million yen)	Share of OTC-like Drugs (A / B) (%)
Herbal/Crude Drugs	1,472	1,472	100
Drugs for Digestive Organs	1,460	5,048	29
Epidermal Drugs	1,457	1,927	76
Allergy Drugs	1,074	1,814	59
Blood and Body Fluid Medicines	1,032	4,699	22
Ophthalmic Medicines	960	2,002	48
Nutritional Tonics	643	648	99
Antipyretic Analgesic Anti-inflammatory Drugs	450	831	54
Vitamins	410	853	48
Hyperlipidemia Medicines	392	2,066	19
Cough Suppressants and Expectorants	291	291	100
Hemorrhoid Medicines	94	94	100
Gargles	24	24	100
Other	694	35,502	2
Total	10,452	57,271	18

Source: Prepared by JRI based on Ministry of Health, Labour and Welfare, "8th NDB Open Data"

(2) Comparison of product characteristics of OTC-like drugs and OTC drugs

As mentioned in the previous section, internal and external drugs can be classified as both medical drugs and OTC drugs based on the manufacturer's application if their active ingredients are low-risk. For this reason, OTC-like and OTC drugs often contain the same active ingredients. This section will compare the prices (costs) and effects of OTC-like drugs and OTC drugs that contain the same active ingredients. The comparisons will mainly be of plain drugs (drugs with one active ingredient), but the characteristics of OTC drugs that are combination drugs (drugs with multiple active ingredients) will also be discussed. With the exception of herbal drugs, almost all medical drugs, including OTC-like drugs, are plain drugs, but many OTC drugs are combination drugs (Watanabe [2020]).

Comparing plain drugs with each other, OTC-like drugs are often cheaper than OTC drugs, resulting in them containing greater amounts of the active ingredients. Generally, OTC-like drugs tend to be more cost-effective than OTC drugs, because the greater the amount of active ingredient contained, the more effective the drug is considered to be.

First, when several common active ingredients, such as acetaminophen (an antipyretic analgesic drug), are compared, the price of the OTC drugs is often about 10 times that of OTC-like drugs (Figure 5). To confirm which is relatively expensive (relatively cheap), wherever possible, drugs containing the same amount of the active ingredient were compared. These amounts are shown in the unit column of the table. Part of the differences in prices between the two reflect differences in pricing methods at pharmacies that inevitably arise due to institutional factors. Since OTC-like drugs are medical drugs, their prices are set by the government, and pharmacies receive a technical fee as compensation for such tasks as dispensing and pharmaceutical management, in addition to the profit they earn from buying and selling the drugs (profit from drug price difference). In the case of medical drugs, on average, the profit from the drug price difference is as low as 6% of the drug price, and the technical fee is less than 40% of the drug cost. In contrast, the selling prices of OTC drugs are freely determined by the pharmacy. Because pharmacies do not receive a technical fee for selling OTC

Figure 5. Price Comparison of OTC Drugs and Medical Drugs

Active Ingredient	Unit	Price (yen)	
		OTC Drug Manufacturer's Suggested Retail Price (incl. Tax)	Medical Drug Official Drug Price in NHI Scheme
Acetaminophen (Antipyretic Analgesic)	Per 300mg Tablet	88.9	6.0
Famotidine (Gastric Acid Secretion Inhibitor)	Per 10mg Tablet	179.7	10.1
Fexofenadine (Pollen Allergy Medicine)	Per 60mg Tablet	103.2	10.1
Loxoprofen Sodium (Compress)	Per 50mg Tablet	138.3	12.3
Arrowroot Tea (Herbal Drug)	Per Tablet	27.1	4.1

Sources: Prepared by JRI based on Ministry of Health, Labour and Welfare, "Information on the List of Drugs Included in National Health Insurance Drug Price Standard and Generic Drugs (applicable from August 1, 2024)" and the websites of each OTC drug manufacturer
Note: Because pharmacies receive a technical fee at the time of sale of medical drugs, a simple price comparison of medical drugs and OTC drugs is impossible.

drugs, they need to set the prices higher to cover expenses such as payroll and store rents and earn profits from the sale of the drugs.

However, the price difference that can be explained by such institutional differences is probably only several times at most, so a price difference as high as around 10 times cannot be explained by institutional factors alone. Another factor is likely to be differences in the cost structures of each manufacturer. Almost all OTC-like drugs are off-patent drugs, and they are produced by generic manufacturers. For generic drug manufacturers, production efficiency is the source of their competitiveness, and in general, they produce on a larger scale and more efficiently than OTC drug manufacturers. Advertising of OTC-like drugs is restricted because they are medical drugs, so advertising expenses are low. On the other hand, for OTC drug manufacturers, adeptness at advertising, such as TV commercials, affects competitiveness to a greater degree than production efficiency does. OTC drugs are often produced on a small scale and at a high cost per unit, so their manufacturers need to sell them at high prices so that they can make a profit even if they spend a lot on advertising.

Next, the amount of the active ingredient contained in OTC drugs tends to be small, because of their original standards for approving them. Therefore, when drugs with the same type of active ingredient are compared, the OTC-like drugs tend to contain more of the active ingredient and be more effective. Although a high level of safety is also required for OTC drugs, the amount sold (in monetary terms) is usually limited, so for the manufacturers, conducting clinical trials to rigorously confirm safety would be too expensive, and they would struggle to make a profit. Since 1970, to ensure safety while also improving the efficiency of the development and review processes, the MHLW has been producing approval standards for major areas of efficacy for OTC drugs (Figure 6).

Figure 6. Approval Standards for OTC Drugs by Efficacy

	Date of Initial Establishment	Date of Most Recent Revision
Cold Medicines	Sep. 1970	Mar. 2015
Antipyretic Analgesics	Nov. 1972	Mar. 2015
Cough Suppressants and Expectorants	Nov. 1976	Mar. 2015
Gastrointestinal Medicines	Apr. 1980	May 2019
Laxatives (Constipation Medicines)	May 1982	Same as left
Antiemetic Drugs (Motion Sickness Prevention)	Jun. 1984	Same as left
Ophthalmic Medicines	Jul. 1986	Same as left
Vitamin-based Medicines	Feb. 1988	May 2019
Enema Formulations	Feb. 1988	Same as left
Anthelmintic Drugs (Deworming Medicines)	Mar. 1989	Same as left
Nasal Sprays for Rhinitis	Feb. 1991	Same as left
Internal Drugs for Rhinitis	Jan. 1993	Mar. 2015
External Drugs for Hemorrhoids	Mar. 1995	Same as left
Medicines for Athlete's Foot and Ringworm	May 1998	Same as left
Herbal Drugs	Sep. 2008	Mar. 2017
Antipruritic and Anti-inflammatory Medicines	Nov. 2011	Same as left
Crude Drugs	Dec. 2017	Same as left
External Analgesic and Anti-inflammatory Medicines	Mar. 2021	Same as left

Source: Prepared by JRI based on Ministry of Health, Labour and Welfare, "Drugs Requiring Guidance and General Drugs" (website)

Regarding these approval standards for OTC drugs, they have been said to "have such a strong influence that they determine the OTC market in Japan" (Takahashi et al. [2001]). The approval standards are essentially a compendium of past approval precedents, and they specify in detail the types of active ingredients that can be included, dosage regimens, and so on. The standards emphasize safety, and the maximum daily dosage of active ingredients that can be included is often set at a much lower level than that permitted for medical drugs (Figure 7). A desire for conservatism is the sole reason that the dosages are set so small, and there is no evidence that higher dosages would exceed the acceptable risk as OTC drugs. Even if a drug does not conform with the approval standards, it may still be approved if it can be confirmed that it is effective and safe and that deviation from the approval standards is necessary[1], but this process may involve clinical trials and costs a huge amount of money. On the other hand, if a drug conforms with the approval standards, the approval authority is delegated to the prefectural governor by the Minister of Health, Labour and Welfare, and the review process is simplified as no clinical trial data are required. For this reason, it is said that most of the OTC drugs that actually reach the market conform with the approval standards (Takahashi et al. [2001]).

Figure 7. Maximum Daily Dose of OTC and Medical Antipyretic Analgesic Drugs

Active Ingredient	Maximum Daily Dose (mg)	
	OTC Drugs	Medical Drugs
Acetaminophen	900	4,000
Aspirin	1,500	4,500
Ibuprofen	450	600
Bromovalerylurea	600	1,000
Tranexamic Acid	750	2,000
Sodium Benzoate Caffeine	300	1,800
Caffeine Hydrate	250	900

Source: Prepared by JRI based on Ministry of Health, Labour and Welfare, "Approval Standards for Manufacture and Sale of Antipyretic Analgesic Drugs," March 25, 2015, Pharmaceutical and Food Safety Bureau Notification 0325 No. 30, attached text from Pharmaceuticals and Medical Devices Agency

As mentioned earlier, it is well known that many OTC drugs are combination drugs. The approval standards for OTC drugs specify relatively small maximum daily dosages of each active ingredient, but various combinations are permitted, and it is common for each company to develop products by mixing multiple active ingredients within the combination patterns allowed by the approval standards. Combination OTC drugs have the advantage of being able to tackle various symptoms with a single product, but pharmacists in the field often say that they are reluctant to recommend them to patients because, for example, the amount of the necessary active ingredient contained is small and active ingredients that are unnecessary are also present. Naturally, if the other conditions are the same, the manufacturing cost of the combination drug will be higher than that of the plain drug.

(3) Problems related to OTC-like drugs

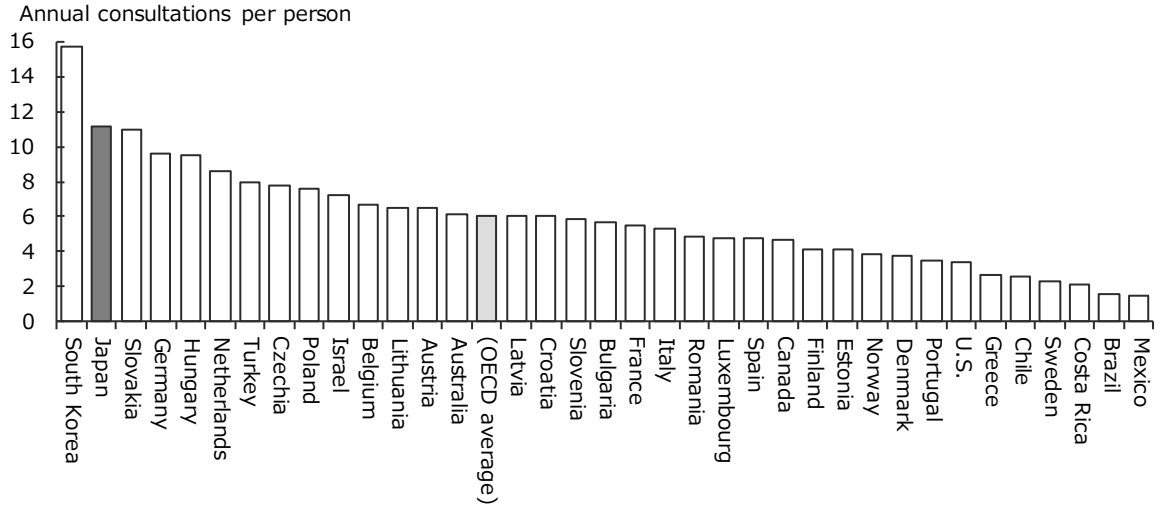
There are four main problems related to OTC-like drugs:

The first is that they impede self-medication. Even if their symptoms can be relieved with an OTC drug, if a patient goes to a medical institution and is prescribed an OTC-like drug, the visit, including the cost of the drug,

[1] Since not only data on efficacy and safety compared to not taking the drug but also data on efficacy and safety compared to cases within the approval standards are required, it can be said to be difficult, as it is more time-consuming and costly.

will be covered by public medical insurance, and they will pay no more than 30% out of pocket. If, on the other hand, they go directly to a pharmacy without visiting a medical institution, consult with the pharmacist, and purchase an OTC drug, it will not be covered by public medical insurance, so they will have to pay the full amount themselves. In other words, self-medication increases patients' out-of-pocket expenses for drugs. In fact, the number of doctor consultations per person is extremely high in Japan (Figure 8), and this is partly due to the low diffusion of self-medication. Workstyle reforms for doctors, which impose upper limits on overtime hours, came into effect in April 2024, and the shortage of doctors is becoming more serious. In light of this, the role of self-medication is becoming increasingly important from the perspective of reducing the burden on doctors.

Figure 8. Average number of in-person doctor consultations per person (2021)



Source: Prepared by JRI based on OECD, "Health at a Glance 2023 OECD INDICATORS"
Note: Data for Japan, Canada, and the U.S. is for 2020.

The second stems from the first, and is that they put pressure on medical insurance finances. When a patient who can deal with their condition with self-medication visits a medical institution and receives a prescription for an OTC-like drug, the cost of the drug is covered by public medical insurance. As mentioned earlier, OTC-like drugs cost 1.0 trillion yen per year. Secondly, costs associated with examinations at medical institutions are pushed up. Even if a patient goes to a medical institution with a mild illness such as a cold and no special tests or treatments are performed, it generally costs more than 3,500 yen. For example, the initial examination fee might be 2,910 yen and the prescription fee might be 600 yen. In addition, the technical fee for the pharmacy will be 2,000 yen. All these costs are covered by public medical insurance. The National Federation of Health Insurance Societies [2023] estimates that for people under the age of 65, the total medical expenditure for consultations at medical institutions that result in only OTC-like drugs being prescribed amounts to 1063.5 billion yen per year (of which 91.9 billion yen is for the OTC-like drugs). As a result of patients going to medical institutions mainly to obtain OTC-like drugs, a phenomenon known as "medicine consultation" in Japan, it is likely that the money spent on compensating medical institutions and pharmacies exceeds the cost of the drugs themselves.

The third is that they undermine the fairness of the public medical insurance system. Enrollment in public medical insurance is compulsory, and since it is funded by taxes and medical insurance premiums compulsorily collected from the people, it is necessary to ensure fairness above all else. As the government promotes self-

medication, a system whereby health insurance, which is also paid for by people who actively strive to self-medicate, covers the drug costs of those who immediately go to medical institution and are prescribed OTC-like drugs even if they only have mild symptoms cannot be described as fair.

The fourth is that they make it difficult for patients to purchase OTC-like drugs directly at pharmacies, which could be a disadvantage for patients. OTC-like drugs tend to be less expensive and more effective than OTC drugs with the same types of active ingredient, so if they could be purchased directly at pharmacies, this would be immensely beneficial for patients who opt for self-medication. However, because they are classified as medical drugs, they are difficult to purchase without a prescription. As mentioned above, the MHLW notice states that the sale of OTC-like drugs in pharmacies without a prescription is only allowed when there are unavoidable circumstances, and most pharmacies respect this.

3. Background to the current classification method

Despite the existence of these problems, why is the standard for determining the need for prescriptions in Japan a double standard, and why are medical drugs the main focus? Before considering measures to address these issues, it is essential to grasp the background. The current situation can be said to be the product of a compromise resulting from the intertwining of historical background with the calculations of industry stakeholders.

(1) Historical background

In 1967, the Ministry of Health and Welfare (a predecessor of the MHLW) announced the "Basic Policy for New Drug Approval' (below, "Basic Policy") in a notice issued by the Director-General of the Pharmaceutical Affairs Bureau, but until then, the classification of "medical drug" did not exist. Apart from prescription drugs (called "drugs requiring direction" at the time, but later rolled into the prescription drugs classification), medical drugs could be sold at pharmacies without any particular restrictions. Moreover, the scope of prescription drugs at that time was limited, and psychotropic drugs and injectable drugs, which are now classified as prescription drugs, could be sold without a prescription in pharmacies at that time (Matsueda [2018]). All that changed in 1967 with the announcement of the Basic Policy. The Basic Policy declared that medical drugs and OTC drugs (officially "general drugs") would be treated separately in the approval review process, and that more emphasis would be placed on safety in the review of OTC drugs. It also prohibited the advertising of medical drugs to the public. The approval standards for OTC drugs in each area of efficacy that were gradually established from 1970 onwards were also based on the Basic Policy.

There were two background factors behind the need for the Basic Policy. One was regret concerning scandals in the 1960s about widespread harm caused by drugs, such as thalidomide and contaminated ampule cold medicine. From the late 1950s to the 1960s, many pregnant women took thalidomide as a sleep aid, but it caused teratogenic side effects, resulting in numerous stillbirths and babies born with deformities. At that time, thalidomide could be prescribed by a doctor or purchased directly at a pharmacy. In addition, in the early 1960s,

pyrine-based cold medicines in glass ampules became popular, and large quantities were sold in pharmacies, but due to their rapid absorption by the body, there were many deaths resulting from shock.

Another was the lack of pharmacist involvement in drug sales. In the 1960s, a price war among drugstores in the Ikebukuro area of Tokyo[2] spread nationwide, resulting in drugs being sold at excessively low prices across the country. As far as one can tell from film footage from that time[3], crowds rushed into stores, with everyone trying to be first to get their hands on the drugs. There was no sign of pharmacists or other experts talking and providing guidance to the consumers seeking drugs. In those days, the pharmacy programs at universities only lasted four years (this was changed to six years from the 2006 intake), and research tended to be emphasized over clinical education (Naruse [2023a]). Therefore, pharmacists did not always have sufficient ability to identify the patient's symptoms and give appropriate advice and guidance, and people did not really expect pharmacists to perform such functions.

However, if the goal was to improve the safety of drugs sold without a prescription, it would be essential to rigorously assess safety during the approval reviews of drugs other than prescription drugs, and to re-classify existing drugs as prescription drugs when necessary, and there was no need to establish the new classification of "medical drugs." Nevertheless, at that time, a massive expansion of the scope of prescription drugs ran the risk of shaking the business foundations of pharmacies. In the 1960s, although medical practice and drug dispensation were notionally separate, boundaries were not enforced. In fact, in-hospital prescriptions, whereby drugs are provided to patients at the medical institutions that examined them, accounted for more than 99% of the total, while out-of-hospital prescriptions, whereby medical institutions issue prescriptions to patients which are then dispensed at pharmacies, accounted for less than 1%. It was therefore difficult for pharmacies at that time to secure sufficient sales through prescription dispensing, and sales of drugs other than prescription drugs made up a large proportion of sales.

The Basic Policy itself contained no wording demanding that pharmacies not sell medical drugs without a prescription unless doing so is unavoidable. However, by regulating the advertising of medical drugs and instructing manufacturers to sell them through distribution routes for medical drugs after they have been approved as medical drugs, it was hoped that improper use caused by such factors as excessive advertising and reckless selling at drug stores would be curtailed. Subsequently, the separation of medical practice and drug dispensation progressed rapidly[4], and it is likely that resistance among pharmacies and pharmacists to measures that made it difficult to sell medical drugs without a prescription faded as pharmacies took on a large role in prescription dispensing. Revisions to the Pharmaceutical Affairs Act (the predecessor of the Pharmaceuticals and Medical Devices Act) in 2005 massively expanded the scope of prescription drugs from about one-third to two-thirds of medical drugs (Tanaka [2005]). Furthermore, a notice was issued that unless there are unavoidable circumstances, medical drugs other than prescription drugs should be sold based on prescriptions.

In this way, until the Basic Policy was established in 1967, in regulations on the sale of drugs, a "medical drug" classification did not exist, but at around that time, the concept of medical drugs was gradually being established in the public medical insurance system. As the public medical insurance system was being

[2] Osaka -based Sankyo Pharmaceuticals opened a store in Ikebukuro, where it sold drugs at low prices. In response, the Tokyo Federation of Pharmacists' Trade Associations opened a store with a similar name, and the competition between the two stores escalated into a price war, with drugs eventually being sold at discounts of up to 90%.
[3] Chunichi-Eiga-Sha, "Medicine Pandemonium" https://chunichieigasha.co.jp/video/4357.
[4] By FY2005, the proportion of prescriptions dispensed at pharmacies had risen to 54%.

established after the war, "Rules for Insured Medical Institutions and Persons in Charge of Insured Medical Treatment and Retirement" (below, "Rules for Persons in Charge of Medical Treatment") were instituted in 1957. These stated that "a panel doctor shall not administer or prescribe to patients drugs other than those specified by the Minister of Health, Labour and Welfare." "Drugs specified by the Minister of Health, Labour and Welfare" refers to drugs included in the National Health Insurance (NHI) Drug Price Standard, which is a list of the drugs covered by public medical insurance, but these drugs gradually came to be recognized as "medical drugs." Later, in 1961, universal insurance was introduced, and as part of that process, the idea that "necessary and appropriate medical care will normally be covered by insurance" came to be formed as the philosophy for universal insurance. Therefore, if there was a need for doctors to prescribe a certain drug, it tended to be included in the NHI Drug Price Standard, even it was a low-risk drug.

As is clear from the above, prescription drugs in the context of Japan's public medical insurance system are no more than drugs on a list of those that can be prescribed by panel doctors and are covered by insurance, and originally there was no direct connection with the risks of drugs. After many twists and turns, the concept of medical drugs came to be used in classifications in regulations on the sale of drugs, which should have been based on risk, resulting in a situation in which it was difficult to sell medical drugs in pharmacies without a prescription.

(2) Calculations of industry stakeholders

The reason that such unique-to-Japan classification methods and sale regulations, which can hardly be described as rational, have been accepted by industry stakeholders such as pharmaceutical companies, medical institutions, and pharmacies is that there are many aspects that serve their ends. There are usually opportunities for representatives of industry associations to become members of the councils and study groups that consider the nature of medical and pharmaceutical-related systems, and to express their opinions at the meetings of these bodies. In addition, MHLW communicates closely with industry stakeholders on a daily basis, making it difficult to implement measures to which industry stakeholders are strongly opposed.

Among pharmaceutical companies, medical drug manufacturers can ensure their products will be covered by public medical insurance if they developed them as medical drugs. This coverage reduces the financial burden on patients and enables the companies to sell more of them. In fact, after the establishment of universal insurance, the amount of insurance benefits allocated to drug costs increased sharply, and in the 1960s some pharmaceutical companies shifted their main business focus from OTC drugs to medical drugs[5]. At the same time, the surge in drug costs put pressure on medical insurance budget finances, and measures to curb drug costs were a frequent topic of discussion. Given such circumstances, if the exactly same drugs are sold directly at pharmacies, talk of excluding them from insurance coverage is apt to arise, so medical drug manufacturers can allay such worries if their products are only made available on prescription. On the other hand, for OTC drug manufacturers, the current classification method and sale regulations confer them the advantage of avoiding competition with highly cost-effective OTC-like drugs. If OTC-like drugs could be easily purchased directly at pharmacies,

[5] Sales of OTC drugs failed to increase due to harmful effects, stricter approval standards, and tougher regulations on their sale.

manufacturers selling OTC drugs with the same type of active ingredients as OTC-like drugs would struggle to sell them at the same high prices as in the past.

Medical institutions, meanwhile, can enjoy more visits from patients, as prescriptions are normally required for patients to obtain highly cost-effective OTC-like drugs. Under the current volume-based medical compensation system, this translates directly into more income. Pharmacies suffer the disadvantage of being restricted in their ability to sell drugs without prescriptions, but thanks to progress with the separation of medical practice and drug dispensation, prescription dispensing is now a key source of revenue for many pharmacies. At present, about 90% of pharmacies in Japan are so-called "doorstep pharmacies," which are either adjoined or very close to medical institutions, so they are not in a position to push strongly for the sale of OTC-like drugs without prescriptions, as this would lead directly to a decline in the revenue of the medical institutions. It is more advantageous for pharmacies to dispense the drugs to patients with prescriptions who have been examined at a medical institution, as they can receive technical fees. However, the public medical insurance system is for insured persons who pay insurance premiums, so it goes without saying that the interests of insured persons should be put before those of industry stakeholders.

4. Required policies

(1) Return from medical drugs to the starting point of prescription drugs

The above discussion has shown that elimination of the double standard for determining the need for prescriptions should be at the heart of the policy measures to be taken to deliver a fundamental solution to the problems surrounding OTC-like drugs. In a nutshell, the classification of medical drugs should be abolished and drugs other than prescription drugs should be classified as OTC drugs. This would constitute a return to the starting point by establishing a simple method of classification. It would result in what are currently known as OTC-like drugs being classified as OTC drugs, and the product group called OTC-like drugs would disappear. After all, pharmacists are also responsible for medical care, and the OTC drugs sold directly by pharmacists are also used in medical care, so the approach of classifying drugs as either medical drugs or OTC drugs makes no sense. This change in the classification method would have the following implications for public medical insurance coverage and measures to prevent improper use:

OTC drugs would continue to be excluded from public medical insurance coverage. This means that the reclassification of what had been OTC-like drugs as OTC drugs would remove them from coverage by public medical insurance as well as from the NHI Drug Price Standard. However, if a drug is necessary for the treatment of a serious illness, the provision of exceptional public medical insurance benefits would be permitted. The Rules for Persons in Charge of Medical Treatment, which panel doctors are supposed to follow, would be relaxed to enable panel doctors to also prescribe OTC drugs. In such cases, the OTC drugs would normally be excluded from public medical insurance coverage, but other costs, such as medical examination fees, would be covered. Overseas, it is common for doctors to prescribe OTC drugs. For example, in Germany, doctors prescribe pink prescriptions for prescription drugs, which are covered by public medical insurance, and green

prescriptions for OTC drugs, which are not covered. In Germany, the volume share of OTC drugs[6] in all drugs sold is 42.5% (2023), of which 7.7% (among the 42.5%) are sold based on doctors' prescriptions (Federal Union of German Associations of Pharmacists [2024]).

Improper use of OTC drugs would be prevented through guidance from pharmacists. To ensure that, a classification for OTC drugs that require a higher level of management, e.g., drugs that are currently OTC-like drugs (below, "OTC drugs requiring management"), would be established, and for an initial period, the pharmacies and pharmacists that can sell such drugs without a prescription would be limited. As mentioned above, since the 2006 intake, pharmacy programs at universities have been six-year programs, and clinical education has been strengthened. Therefore, more pharmacists or pharmacies should be able to assess patients' symptoms, select the drugs they should take, and provide them with appropriate guidance on how to take them. "Health support pharmacies" would be strong candidates for pharmacies that can sell OTC drugs requiring management. A health support pharmacy is a pharmacy that is recognized for its ability to support self-medication. It needs to meet requirements such as centralized management of patient drug histories (i.e., the drugs that the patient has taken in the past), including OTC drug history, presence of pharmacists who have undergone specific training, operation at night and on holidays, and cooperation with medical institutions. For OTC drugs requiring management, the pharmacies selling them would have to record sales in patient drug histories, and within a few years, infrastructure, such as an electronic prescription system, would be established so that histories can be easily shared with external medical institutions and pharmacies whenever necessary.

(2) Expected effects

Such reforms could be expected to solve various problems. First, by excluding what are now OTC-like drugs from public medical insurance coverage, self-medication would be promoted, the system would be fairer, and the cost of public medical insurance benefits would be curbed.

Digging deeper into the effects of curbing the cost of public health insurance benefits, a reduction in outpatient visits could be expected to lead to less spending on medical examination fees and pharmacy technical fees (indirect effects), but it is difficult to predict the specific amounts. On the other hand, the reduction in the amount of drug benefits (direct effect) due to the exclusion of OTC-like drugs from public health insurance coverage alone would be expected to be about 1.0 trillion yen. Assuming that the shares of this saving are the same as the shares of the funding of total national medical expenditure[7], the burden reductions would be 500 billion yen for medical insurance premiums and 380 billion yen for public expenses, for a total of 880 billion yen (out-of-pocket expenses account for the remaining 120 billion yen[8]). As mentioned at the beginning of this paper, the government collects one trillion yen per year to fund child/childcare support by adding it to medical insurance premiums, which means that even if only the direct effects of the reforms are taken into account, the burden of medical insurance premiums could be reduced by half of that figure, i.e., by 500 billion yen. As for the reduction of the public expense burden, in line with a policy of limiting the real increase in social security-

[6] In Germany, both prescription and OTC drugs are sold in boxes (packages), so the volume share is the share of the number of boxes.
[7] By funding source, the shares of the national medical expenditure of 45.4 trillion yen in FY2021 were 50% for insurance premiums, 38% for public expenses, and 12% for other (e.g., patients' out-of-pocket expenses).
[8] Since patients pay the full amount out of pocket when purchasing OTC drugs, this cannot be said to be a reduction in burden.

related expenses to the increase due to the aging of the population, the government has been implementing measures to curtail social security-related expenses by the mid-100 billion yen level by altering and streamlining the system (Figure 9), so 380 billion yen is equivalent to two to three years of those annual curtailment.

Second, patients would be able to easily purchase what are now OTC-like drugs, which are highly cost-effective, at pharmacies, so patients who actively try to self-medicate would be expected to benefit. The exclusion of OTC-like drugs from public medical insurance coverage has been discussed from time to time for many years, but this would likely lead to the disappearance of highly cost-effective OTC-like drugs (as they are called now) from the market, making it impossible for patients to use them. The biggest difference between the proposal to simply exclude them from public medical insurance coverage and the proposal, argued for in this paper, to overhaul the classifications themselves can be said to be that the latter proposal would allow what are now OTC-like drugs, which are highly cost-effective, to be used effectively as OTC drugs.

Figure 9. Amount of Curtailment of Social Security-related Budget Due to Institutional Reform and Efficiency Improvement (Initial Budget Basis)

(100 million yen)

FY2023		FY2024	
Drug Price Revision	-700	Revision of Drug Prices etc. and Reform of Drug Price System	-1,300
Review of Patients' Out-of-pocket Expenses for Medical Care for Old Elderly Persons	-400	Compensation Adjustment for Benefits for Young Elderly Persons	-1,300
Review of Exemptions Such as Employment Adjustment Subsidies	-300	Expansion of Application of Employees' Insurance	-100
Grants to Improve Functions of Insurers (Nursing Care)	-100	Revision of Medical Care Compensation	600
Review of Criteria for Livelihood Assistance	100	Revision of Nursing Care Compensation	200
		Revision of Compensation for Disability Welfare Services etc.	200
		Support for Health Insurance Societies	200
Total	-1,500	Total	-1,400

Source: Prepared by JRI based on Ministry of Finance, "Government Budget Draft (Social Security-Related Budget)"
Note 1: Only key measures are presented, and figures have been rounded, so the sum of the figures does not match the total.
Note 2: - indicates budget curtailment.

(3) Possible criticisms and ways of addressing them

Since the reforms proposed in this paper are radical, their impacts would be multifaceted and they would probably be criticized. Below, the three main criticisms that would likely be heard are examined, and ways of addressing them are considered:

First, there would be concern about an increase in drug costs due to changes in doctors' prescribing behavior. If OTC-like drugs become OTC drugs and are no longer covered by public medical insurance, doctors might prescribe substitutes that are covered by public medical insurance (prescription drugs) in order to reduce the financial burden on patients. Prescription drugs are generally more expensive than OTC-like drugs, so if this

became a widespread trend, the drug bill for public medical insurance would increase, which would be the opposite of what was intended.

Doctors in Japan tend to prescribe drugs in a laissez-faire manner, and little consideration is given to curbing the drug costs covered by public medical insurance (Naruse [2023b]). But this situation itself is very different from that in other countries. It is a serious problem and should be corrected immediately. In the U.K. and Germany, for example, emphasis is placed on formularies, which are lists of recommended medicines that are compiled after taking costs into account. Local medical organizations manage budgets for medical expenses, including drug costs, and monitor and provide guidance concerning the drugs administered at each medical institution. Meanwhile, in South Korea, the situation used to be similar to Japan, with numerous inefficient prescriptions, but medical compensation was employed to guide doctors, and gradually prescriptions came to be used efficiently (Naruse [2023b]).

In Japan, too, the government needs to produce a formulary and doctors will need to respect it. The formulary would ensure that OTC drugs are used for patients with symptoms that can be treated with OTC drugs. And to make sure the formulary is properly adhered to, the prescribing behavior of doctors would need to be monitored, with penalties imposed for inappropriate behavior. Data from public medical insurance claims (medical compensation statements) would be statistically analyzed, and medical institutions that frequently deviate from the formulary or claim more in drug costs than would be expected given factors such as the number of patients treated would be instructed to correct their behavior. If necessary, penalties such as reductions in medical compensation or, in egregious cases, the stripping of insured medical institution status would be imposed. In the initial period after the abolition of the medical drug classification, the focus would be on verifying that prescriptions have not just shifted to drugs that can be used as substitutes.

Second, critics would point to a possible deterioration in access to medical care, and in particular, access to what had previously been OTC-like drugs. To start with, some argue that excluding OTC-like drugs from insurance coverage would discourage patients from consulting doctors, and that they would therefore be more likely to become seriously ill (Murakami [2021]), but given the nature of the proposal presented in this paper, this is a groundless fear. This is because the proposal would not exclude medical examination fees from insurance coverage, so even if a patient ultimately turned out to only have a mild illness when they had been worried about it and sought medical help, the cost of that consultation would still be covered. Although the proposal in this paper would appear to curtail so-called "medicine consultations," i.e., visits to medical institutions for the sole purpose of obtaining OTC-like drugs, no aspect of it would deter patients who are worried about becoming seriously ill from going to medical institutions due to financial reasons.

Next, in the sense that the out-of-pocket burden of drug costs would increase, it cannot be denied that access to what had been OTC-like drugs, which would no longer be covered by insurance, would worsen to some degree[9]. However, OTC-like drugs are generally not used for the treatment of serious diseases, and given their low cost, this adverse impact is probably within the acceptable range. Overseas, OTC drugs are not eligible for benefits in the public medical care systems of many countries, and this is because of the above-described nature of OTC drugs. Under the proposal presented in this paper, if a drug is necessary for the treatment of a serious

[9] If a person used to go to a medical institution and receive a prescription for an OTC-like drug, but changed their behavior by going directly to a pharmacy and purchasing it there, then if only the drug cost is taken into account, their out-of-pocket burden would increase, but in terms of the total cost, including the medical examination fee, it is perfectly possible that the burden would decrease.

illness, the provision of exceptional public medical insurance benefits would be permitted, and this could mitigate any adverse impact on access.

Third, there would be concern about damage to health resulting from improper use of OTC-like drugs. OTC-like drugs tend to contain large amounts of the same active ingredients as OTC drugs, so harm to health could be substantial in cases of improper use. However, even OTC-like drugs that are currently classified as medical drugs are not permitted to contain doses that are large enough to significantly increase risk. If an OTC-like drug has been used for many years as a medical drug and there have been no major problems so far, then even if it is reclassified as an OTC drug, as long as there is appropriate guidance from pharmacists, excessive concern is likely to be unwarranted. Ways of ensuring that pharmacists provide proper guidance are as presented in the previous section.

5. Conclusion

As the above has shown, elimination of the double standard, i.e., abolition of the classification of medical drugs, is the key to solving various problems. However, unless the conventional practices of doctors prescribing drugs in a laissez-faire manner and pharmacists providing insufficient guidance to patients are abandoned, the disadvantages will probably outweigh the advantages. Rather, the fact that the medical drug classification came into being can actually be viewed as a result of those conventional practices. That being the case, the classification of medical drugs can be seen as meaningless, as it arose out of the inappropriate nature of the ways doctors and pharmacists in Japan are involved in drug therapy. If doctors prescribed drugs in a standardized fashion and pharmacists provided patients with sufficient guidance, the classification would naturally become unnecessary. Therefore, while the abolition of the classification of medical drugs is a reform that poses challenges, it would likely be a catalyst for making drug therapy in Japan more appropriate, as it would call for the education of stakeholders such as doctors and pharmacists and for their cooperation to be obtained.

Addendum: Comparison of OTC-like drug market size estimation in this paper with previous studies

In this paper, the size of the market for OTC-like drugs in Japan was estimated at 1.0 trillion yen, but previous studies have also presented estimates of the OTC-like drug market size. However, as was pointed out in the body of this paper, the definition of OTC-like drugs tends to be vague, and estimation results will naturally vary if the scope of drugs considered to be OTC-like drugs is different. In addition, estimation results will also be affected by the database used. The following will focus on the scope of OTC-like drugs and the database used for estimation, and highlight the characteristics of the estimation performed in this paper by comparing it with two important previous studies. Note that since both previous studies used data derived from medical compensation statements as in this paper, the size of the market for OTC-like drugs is based on drug prices.

The first of the previous studies was one by Igarashi et al. titled "Research on the creation of infrastructure for assessing the effect of medical expense optimization through tax breaks for self-medication." It was

contained in a general research report concerning subsidies for health, labor, and welfare administrative promotion research projects (special research projects in health, labor, and welfare sciences). Although the study did not use the term OTC-like drugs, it estimated, using a private commercial database of medical compensation statements (from JammNet Co., Ltd.), the size of the market for medical drugs with the same active ingredients as OTC drugs at 651.3 billion yen (Figure 10). The database contained (at that time) data on about five million people enrolled in society-managed health insurance.

Figure 10. Comparison of Estimate in This Paper Concerning OTC-like Drugs with Previous Studies

	Estimate in This Paper	Igarashi, Ataru; Wada, Ichiro; Goto, Rei; Ibuka, Yoko; and Bessho, Shun-ichiro [2023]. "Research on the creation of infrastructure for assessing the effect of medical expense optimization through tax breaks for self-medication" (contained in a general research report concerning subsidies for health, labor, and welfare administrative promotion research projects (special research projects in health, labor, and welfare sciences))	National Federation of Health Insurance Societies [2023]. "Survey study VI (report) on analysis of medical compensation statements to facilitate policymaking"
Definition	Medical Drugs Other than Prescription Drugs	Medical Drugs with The Same Ingredients as OTC Drugs	Medical Drugs for which OTC Versions are on Sale
Database	NDB Open Data	JammNet's Commercial Database of Medical Compensation Statements	Medical Compensation Statement Data Collected from 118 Health Insurance Societies
Domestic Market Size / Aggregate Figure	Domestic Market Size and Aggregate Figure	Domestic Market Size	Aggregate Figure
Period	FY2021	FY2020	Oct. 2021 - Sep. 2022
Amount (100 million yen)	10,452	6,513	453

Sources: As stated in the figure

The second of the previous studies was "Survey study VI (report) on analysis of medical compensation statements to facilitate policymaking," and was conducted by the National Federation of Health Insurance Societies. The study defined OTC-like drugs as "among drugs covered by insurance, medical drugs for which OTC versions are sold." Such drugs would probably at least have to contain the same types of active ingredient as OTC drugs, but the definition does not make it clear which of elements such as the amount of the active ingredient contained, efficacy, dosage, additives, form, manufacturer, etc. would need to be the same for a drug to be classed as an OTC-like drug. As a result of aggregating data from medical compensation statements collected from October 2021 to September 2022 with the cooperation of 118 health insurance societies, the amount of prescriptions for OTC-like drugs was found to be 45.3 billion yen. It needs to be noted that this amount is not the market size for Japan as a whole, as it is just the amount of prescriptions in the medical compensation statements that were analyzed.

The characteristics of the estimation performed in this paper compared to the above previous studies are as follows: First, the scope of drugs deemed to be OTC-like drugs is broad, and it is easy for third parties to determine whether each item constitutes an OTC-like drug. For the estimation performed in this paper, OTC-like drugs are medical drugs other than prescription drugs, and they include many drugs that contain the same types of active ingredient as OTC drugs, but also a considerable number of drugs that do not. Therefore, the scope of OTC-like drugs in this paper is probably broader than that in the two previous studies. As a result, the estimated market size is also higher than that in the previous study by Igarashi et al.

There are approximately 13,000 OTC drugs, many of which contain multiple active ingredients, and no list of active ingredients included in OTC drugs could be found. Therefore, using the definition from the previous studies, it is difficult for third parties to determine whether each medical drug constitutes an OTC-like drug. In contrast, it can be easily confirmed, from the package insert, whether a drug meets the definition of OTC-like drugs used in this paper, i.e., medical drugs other than prescription drugs. This ease of confirmation by anyone can be regarded as positive, as it allows discussions on policies related to OTC-like drug classification and the nature of insurance benefits, as well as the impact of these policies, to move forward based on a common understanding.

Next, while both this paper and the previous studies employed data from medical compensation statements, the NDB open data used for the estimation performed in this paper has the following two characteristics: First, it has a high degree of completeness. Since NDB open data includes medical compensation statements from all insurers, the aggregated figure can be regarded as more or less representative of the size of the domestic market for OTC-like drugs. In contrast, the databases used in the two previous studies contained medical compensation statements collected from a limited number of insurers, so the aggregated figures cannot used as proxies for domestic market size. Because people of working age comprise the bulk of those enrolled in health insurance society-managed insurance, some ingenuity would seem to be needed to estimate the size of the domestic market, which includes elderly people, from those figures. Second, as its name suggests, NDB Open Data can be accessed by anyone and can be verified and reproduced. Since the databases used in the previous studies were a private fee-charging database in one of the studies and a database comprising data held by insurers in the other, only certain people can access them.

(October 22, 2024)

References

[1] Akagi, Kazuko [2016]. "Transformation of the pharmacist function in postwar Japan: from the perspective of the historical development of the separation of medical practice and drug dispensation."

[2] Igarashi, Ataru; Wada, Ichiro; Goto, Rei; Ibuka, Yoko; and Bessho, Shun-ichiro [2023]. "Research on the creation of infrastructure for assessing the effect of medical expense optimization through tax breaks for self-medication" (contained in a general research report concerning subsidies for health, labor, and welfare administrative promotion research projects (special research projects in health, labor, and welfare sciences)).

[3] Institute for Health Economics and Policy [2023]. "Survey study report on the drug use status etc." (project undertaken for the Medical Economics Division of the Health Insurance Bureau of the Ministry of Health, Labour and Welfare in FY2022).

[4] National Federation of Health Insurance Societies [2023]. "Survey study VI (report) on analysis of medical compensation statements to facilitate policymaking."

[5] Takahashi, Toshinobu; Hyakushima, Toru; and Komoto, Keisho [2001]. "The role of popular medicines and drug regulation in self-medication," NLI Research Institute Report Vol. 17.

[6] Tanaka, Hideaki [2005]. "The mystery of 'prescription drugs.'"

[7] Naruse, Michinori [2023a]. "Nature of the supply of pharmacists: crafting a vision for the future of pharmacists, halve the number of pharmacy faculties, and strengthen clinical education," JRI Review, 2023, Vol. 4, No. 107.

[8] Naruse, Michinori [2023b]. "Breaking away from overemphasis on drug prices in pharmaceutical benefits scheme: limiting coverage and call for improving doctors' prescribing behavior," JRI Review, 2023, Vol. 8, No. 111.

[9] Nishizawa, Motohito [2007]. "General drugs and pharmacists," Journal of Pharmaceutical Science and Technology, Japan, Vol. 67, No. 2.

[10] Matsueda, Akiko [2018]. "Historical research on the transformation of the societal role of nonprescription drugs."

[11] Murakami, Masayasu [2021]. "On the review of insurance benefit scope focusing on drugs," Japan Medical Association Research Institute Research Report, No. 111.

[12] Watanabe, Kinzo [2020]. "Recent social background and general consumer awareness of OTC drugs and self-medication," Yakugaku Zasshi, Vol. 140, No. 3.

[13] Federal Union of German Associations of Pharmacists [2024]. "GERMAN PHARMACIES FIGURES・DATA・FACTS2024"