Five Policy Proposals to Combat Proliferation of Counterfeit Drugs from Private Importation and Promote Rx-to-OTC Switch in Japan

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Summary

With the ongoing effects of the COVID-19 pandemic and access to healthcare facilities still facing restrictions, self-medication has gained attention. With this backdrop, the Japanese government has shown a proactive approach to the promotion of self-medication and has announced the "acceleration of Rx-to-OTC switch drugs" as a key policy. However, as of 2023, Japan's universal health insurance coverage system and free access to hospitals has made it easy to visit a doctor even for minor illnesses, leading to a mere 6.9% of all drugs being over the counter (OTC), the lowest among G7 nations, with no significant signs of change. As a result, various issues have arisen, such as increased financial strain of the health insurance system, increased outpatient consultation times, and difficulty accessing drugs in a timely manner. In this policy proposal, we will cover the issue of private importation of drugs, which is often overlooked when discussing the promotion of self-medication and Rx-to-OTC switch. We hope to propose the direction to take the OTC drug approval system and self-medication promotion initiatives, from the perspective that the expansion of Rx-to-OTC switch and OTC drugs will help to accelerate the adoption of self-medication, as well as prevent damages caused by the private importation of counterfeit drugs.

The majority of privately imported drugs are not approved in Japan and some are counterfeit drugs. A common reason for private importation is the inability to buy the genuine drug easily at drug stores. We believe the cause for private importation is the limited availability of convenient methods to purchase genuine drugs, which in turn, can lead to the spread of issues caused by counterfeit drugs. In addition, the purchase of drugs online is becoming more commonplace, and is predicted to become more widely adopted, which is likely to lead to more health risks caused by privately imported counterfeit drugs. For this reason, it can be said that there is an urgent need to increase avenues to purchase genuine medicine through Rx-to-OTC switch, in order to protect citizens from off-label and counterfeit drugs.

We believe there are three main reasons for the unfavorable progress in Rx-to-OTC switch in Japan. First, is the lack of government goals and clear roadmap for Rx-to-OTC switch. Another factor is the ambiguity surrounding the specific topic of discussion that will be addressed at the Evaluation Council Regarding the Switch from Prescription Drugs to Drugs Requiring Guidance or Over-the-Counter Drugs (hereinafter, the Evaluation Council). Third, is the lack of a set deliberation deadline for the Evaluation Council. As a result, for example, discussions by the Evaluation Council regarding emergency contraceptives have lasted for a total of approximately six years.

In addition, the proposal will cover two possible issues that may arise due to the promotion of Rx-to-OTC switch. First, is the lack of a forum to discuss challenges and possible solutions regarding the promotion of OTC drugs, leading to the lack of a way to amass and share evidence regarding OTC drugs, and unclear direction when deciding how to best utilize OTC drugs in Japan. Another issue is the absence of a system that considers over-the-counter drugs being used by patients when prescribing medication, which increases the risk of prescribing drugs that may have adverse interactions.

With these challenges in mind, this policy proposal suggests the implementation of the following five policies.

1. Establishment of a Rx-to-OTC Switch Roadmap Committee and the prompt development of KPIs and roadmap for Rx-to-OTC switch
2. Evaluation Council restructuring (implementation of a target timetable for considerations, clarification of discussion topics required to achieve KPIs, creation of a deadline from submission of written proposal to start of deliberation)
3. Creation of an OTC drug database
4. Creation of an OTC pharmaceutical record book in line with the self-medication tax system
5. Creation of a Japanese OTC Pharmaceutical Society

We hope the policies set forth in this policy proposal will initiate discussions on promoting self-medication in a way that aligns with the Japanese society and will help to contribute to the sustainability of the medical care provision system and universal health insurance system.

Section 1　The Need for Promotion of Self-Medication

The declining birthrate and aging population in Japan are issues that concern all citizens. By 2040, approximately 35% of the Japanese population will be over 65 years of age, and each older adult will need to be supported by 1.5 working-age people (known as the "Year 2040 problem"). This situation may cause Japan to face a serious labor shortage. Regarding healthcare, the number of older adults aged 85 years and above is expected to exceed 10 million by 2040, leading to an increase in medical needs. As a result, a shortage of healthcare professionals, including physicians, may cause an imbalance between medical demand and supply, making it impossible to maintain the current medical care provision system[1]. From a financial perspective, medical expenses required owing to increasing medical needs are expected to reach 66.7 trillion yen, which is 1.6 times the 39.2 trillion yen in 2018, as estimated by the Ministry of Health, Labour and Welfare of Japan (MHLW) [1,2]. Against this background, the government has begun actively promoting self-medication practices. This chapter discusses why the promotion of self-medication practices is of vital importance to modern Japanese society.

1-1. The Relationship Between COVID-19 and Self-Medication

Following the first case reported in China in December 2019, the novel coronavirus (COVID-19) spread throughout the world, including Japan. The virus placed heavy restrictions on people's lives, and those restrictions also affected healthcare facilities. The lack of staff due to the infection of nurses and other healthcare professionals meant that not only were COVID-19 patients unable to be accepted at medical facilities, but other patients also could not be accepted, and the entire healthcare system was heavily strained. Many patients avoided visiting hospitals altogether in a phenomenon that was called "jushin-hikae" in Japan.

With the prolonged effects of COVID-19 and the continued restrictions in accessing medical care, the necessity for self-medication is being reaffirmed. The MHLW defines self-medication as the "recognition of the responsibility of individuals for their own health...and self-reliance in preventing or relieving minor symptoms or conditions," and self-medication can provide many benefits as described below[3].

1-2. Maintaining a Sustainable Medical Care Provision System

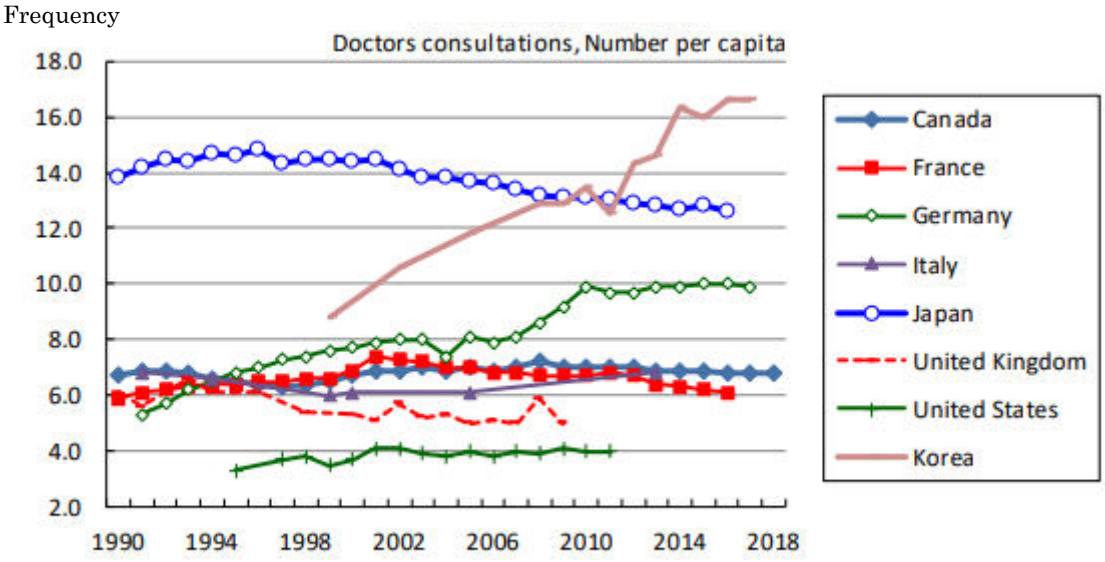
First, self-medication is expected to reduce the strain on healthcare facilities and create a sustainable medical care provision system. Recently, labor shortages and aging healthcare professionals have caused increasing pressure on healthcare facilities. While labor shortages caused by Japan's rapidly shrinking workforce has affected all industries, the healthcare industry has been hit particularly hard. The number of doctors per 1,000 people in Japan ranks among the lowest of all Organisation for Economic Co-operation and Development (OECD) members. At 2.49 doctors per 1,000 people, Japan has less than half the number of doctors compared to Australia and Norway, which rank No. 1 and No. 2, respectively, clearly demonstrating a lack of doctors in the country[4]. At the same time, the percentage of the population aged 65 or older in Japan was only 5% in 1950, grew to 14% in 1994, and has currently reached approximately 30%[5]. If this current trend of a lack of healthcare professionals and a rapidly growing aging population continues, it is obvious that the medical care provision system cannot be sustained. According to OECD data on the number of doctor

consultations per capita, Japan is the second highest behind Korea in the number of doctor consultations[6] (Figure 1). One can infer from this data that self-medication has not been widely adopted within Japan. Further, it can be assumed that promoting self-medication and increasing the number of medical products for self-medication will reduce the number of patients visiting doctors for continued use of prescribed medicine, which will also help to reduce the strain on healthcare professionals. In addition, the promotion of self-medication may push individuals to be more active in their own health care, allow for early discovery of serious illnesses, and aid in early treatment of illnesses before they become more severe, again leading to reduced strain on healthcare professionals.

In Europe, there is a study investigating whether the use of self-medication contributes to reducing the burden on medical workers. The study estimates that patient self-medication for minor illnesses saves GPs across Europe by around one hour of work time per day. It has been suggested that this reduced working time can be used to treat serious illnesses[7] (Chart 1)

Furthermore, starting in April 2024, new restrictions will be placed on doctors working overtime or working on weekends, which will likely reduce the number of patients each doctor can see. The promotion of self-medication is urgently needed in order to support doctors in achieving these workstyle reform policies.

Figure 1. Doctor consultations, number per capita



Data from OECD Health Statistics 2019

(Source: Maeda, Y. (2019, September 17). *Iryōkanren dēta no kokusaihikaku－OECD Health Statistics 2019－* [Global Comparison of Data Relating to Healthcare -OECD Health Statistics 2019-]. Japan Medical Association Research Institute.)

Chart 1. Self-Medication in Europe: Economic and Social Impact on Individuals and Society

▶ **Table 2** Cost savings in the status quo – Europe total

Cost Savings in the Status Quo Scenario		
	Substitution volume of MAs per year	**1.19 bn**
Direct Cost	Total medication cost (EUR)	−6.21 bn
	Treatment cost GP (EUR)	−20.10 bn
Indirect Cost	Time cost GP (hours)	−221.25 m
	Treatment-related work loss (EUR)	−4.65 bn
	Treatment-related work los (hours)	−191.92 m
	Absence from work due to sick leave (EUR)	−5.76 bn
	Absence from work due to sick leave (hours)	−237.83 m
Intangible Cost	Time cost patient (hours)	−2.10 bn

(Source: Uwe May,et al, 「Self-Medication in Europe: Economic and Social Impact on Individuals and Society」 Thieme: Gesundheit ökon Quality management, DOI 10.1055/a-2089-)

1-3. Maintaining the Universal Health Insurance Coverage System

Secondly, the promotion of self-medication plays an important role in maintaining a sustainable and stable universal health insurance coverage system. According to the Ministry of Health, Labour and Welfare (MHLW), national healthcare expenditure

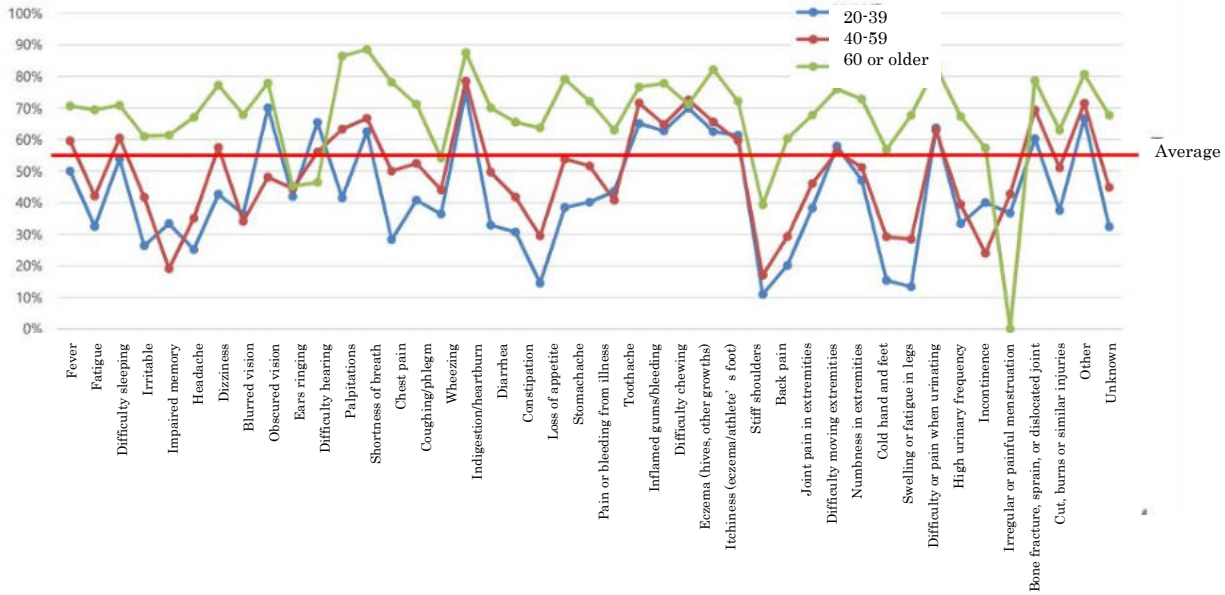
reached 4.43 trillion yen in 2019, an over two-fold increase when compared to 1989. Expenditure is estimated to reach 6.85 trillion yen by 2040, rising together with the growing aging population in the country[8,9]. With the rapidly declining younger generation that bear the costs of universal health insurance, reducing healthcare costs is a necessary step in order to sustainably maintain social security benefits.

As shown in Figure 2, the percentage of patients over 60 that went to see a doctor for common symptoms is higher than those aged between 20 and 59, and it is likely that a percentage of those visits are for mild symptoms. In addition, as shown in Figure 3, while people in their 50s and 60s make up more than half of those using medical expense deductions, people in their 30s and 40s make up more than half of those who utilize the self-medication tax system（The "Self-Medication Tax System" in Japan is a special case of medical expense deductions. It allows individuals who engage in certain health maintenance and disease prevention activities to receive income tax deductions for the cost of purchasing specific over-the-counter (OTC) medicines）[10]. The reasoning is likely that as shown in Figure 2, most people over 60 tend to see a doctor for illnesses, and the number of visits are higher than those in their 30s and 40s, increasing the times the deductions would be used. This is compared to the working population in their 30s and 40s, who are likely to have less time to visit doctors and are more likely to manage their own health. As a result, the self-medication tax system is slowly increasing in usage in this age group. This, in addition to the copayment being lower for older patients, leading to higher frequency of doctor visits, are believed to have heavily impacted the financial state of the healthcare system. This data shows the importance of promoting self-medication and decreasing the number of doctor consultations for the 60 and older age group.

In addition, the lifetime healthcare costs per capita is approximately 27 million yen, and there are studies that show that over half of those costs are incurred in the 10 or more years after reaching the age of 70[11]. The likelihood of being diagnosed with lifestyle diseases, chronic illnesses, and other complications increase with age, and treatments for those illnesses can be costly. If citizens are able to use self-medication to treat lifestyle diseases and chronic diseases before they become severe, it can contribute to the reduction of healthcare costs, and in turn maintain the sustainability of the healthcare system's finances and the universal healthcare system as a whole.

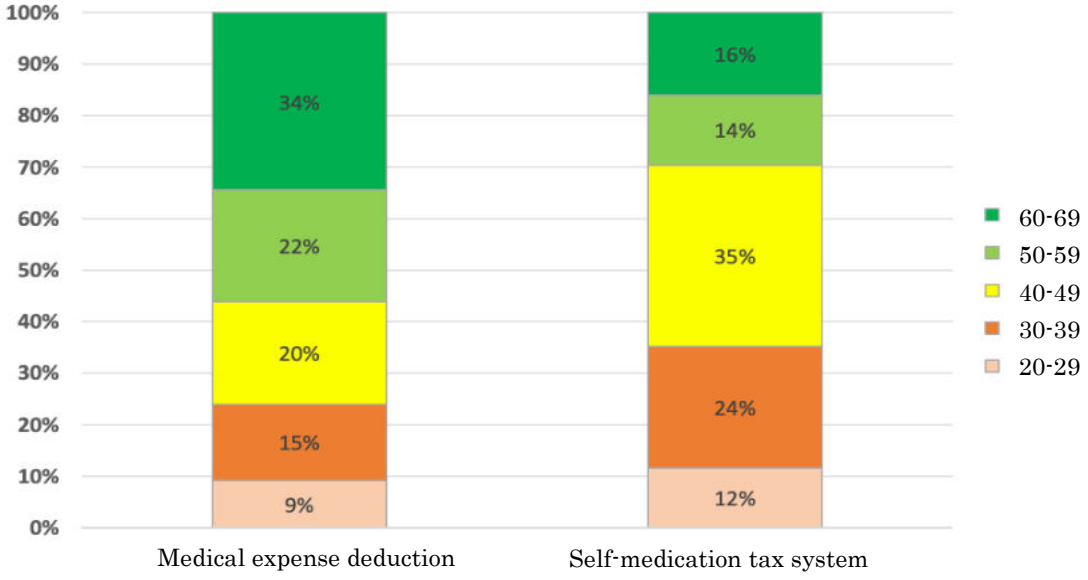
In addition, the reduction of healthcare costs through self-medication is in line with the "wise spending" process outlined in the Economic and Fiscal Revitalization Action Program announced by the Committee for Promoting the Integrated Economic and Fiscal Reforms on December 16, 2015 [12]. Within the Action Program, it is clearly stated that as a part of realizing wise spending, promoting behavioral change is required to optimize spending on medical and nursing care services without lowering their quality, including incentive-based systems for early prevention diseases[12]. With various groups voicing concerns on the financial state of the healthcare system and sustainability of the universal health insurance system in a country with a growing aging population and declining birthrate, promoting wise spending through the self-medication is crucial.

Figure 2. Percentage of Doctor Consultations by Symptom



(Source: Ministry of Health, Labour and Welfare, Health Policy Bureau, Economic Affairs Division. (2021, February 3). *Serufumedikēshon zeisei no minaoshi ni tsuite* [Re-examination of the Tax System on Self-Medication].)

Figure 3. Age distribution of medical expense deduction and self-medication tax system use



(Source: Ministry of Health, Labour and Welfare, Health Policy Bureau, Economic Affairs Division. (2021, February 3). *Serufumedikēshon zeisei no minaoshi ni tsuite* [Re-examination of the Tax System on Self-Medication].)

1-4. Increase in Health Consciousness

Thirdly, the promotion of self-medication meets the needs of citizens who have a higher sense of health consciousness following the COVID-19 pandemic. With the long-lasting restrictions to healthcare access due to the pandemic, there was a shift in attitudes towards health. According to research conducted by the National Federation

of Health Insurance Societies in 2021 regarding changes in doctor consultations following the COVID-19 pandemic, 39.2% responded that they believe "they are more concerned with preventing lifestyle diseases," and 4.7% responded that they believe "they are more likely to use generic drugs." In regard to online consultations, 12.0% responded that they believe "they are likely to consider online consultations," and 6.4% responded that "they are more likely to consult regarding personal health," revealing that in addition to higher health consciousness, there is more interest in using OTC drugs and online consultations[13]. After witnessing a strained medical care system, there is a stronger sense of self-responsibility and taking actions for disease prevention.

In addition, changes in lifestyle such as increased flexibility in workstyles has further spurred the need for the promotion of self-medication. The COVID-19 pandemic created major change in the way people work, and in 2022, 50% of workers in Tokyo, 20% of workers in rural areas of Japan were working remotely[14]. Due to the effect of quarantine measures during the pandemic, companies have implemented more flexible work styles including remote work, which has also affected people's lifestyles outside of work. According to a survey conducted by the Japanese Cabinet Office regarding interest in moving to more rural areas, 11.8% of people in their 20s living in Tokyo's 23 wards responded that they have "increased interest," and 23.6% responded that they are "somewhat interested." Out of respondents in their 20s living in the Greater Tokyo Area (Tokyo, Kanagawa, Chiba, and Saitama), 27.7% responded that they have "increased interest" [14]. However, there is currently an issue of doctor shortages in rural areas, and as shown in Chart 2, there is also an unequal distribution of doctors [15,16].

Chart 2. Doctor distribution index by prefecture

Doctor distribution index by prefecture

High number of doctors (>244.8) | Low number of doctors (<215.3)

Prefecture	Dist. Index	Ranking	Prefecture	Dist. Index	Ranking	Prefecture	Dist. Index	Ranking	Prefecture	Dist. Index	Ranking
Tokyo	332.8	1	Tottori	256.0	13	Ehime	233.1	25	Nagano	202.5	37
Kyoto	314.4	2	Kumamoto	255.5	14	Kanagawa	230.9	26	Chiba	197.3	38
Fukuoka	300.1	3	Kagawa	251.9	15	Aichi	224.9	27	Shizuoka	194.5	39
Okayama	283.2	4	Shiga	244.8	16	Yamanashi	224.9	28	Yamagata	191.8	40
Okinawa	276.0	5	Hyogo	244.4	17	Hokkaido	224.7	29	Akita	186.3	41
Osaka	275.2	6	Oita	242.8	18	Toyama	220.9	30	Ibaraki	180.3	42
Ishikawa	272.2	7	Nara	242.3	19	Yamaguchi	216.2	31	Fukushima	179.5	43
Tokushima	272.2	8	Hiroshima	241.4	20	Tochigi	215.3	32	Saitama	177.1	44
Nagasaki	263.7	9	Shimane	238.7	21	Mie	211.2	33	Aomori	173.6	45
Wakayama	260.3	10	Miyagi	234.9	22	Gunma	210.9	34	Iwate	172.7	46
Saga	259.7	11	Kagoshima	234.1	23	Miyazaki	210.4	35	Niigata	172.7	47
Kochi	256.4	12	Fukui	233.7	24	Gifu	206.6	36	Japan Total	239.8	—

Based on: Study Group on Supply and Demand of Medical Workers. 35th Medical Supply and Demand Subcommittee. (2020, August 31). file3. *Doctor distribution index through the Medical Security Plan*, and Takuya Shinohara. (2022, May 17). *Balance between supply and demand of physicians 2022: What steps are being taken to correct physician maldistribution?*

(Source: Shinohara, T. (2022, May 17). *Ishi no juyō baransu 2022—ishihenzai zesei no tame ni donoyōna tedate ga kōjirareteiruka?* [Balancing the demand for doctors 2022 – What measures are being taken against the uneven distribution of doctors?]. NLI Research Institute.)
(Source: Ministry of Health, Labour and Welfare. (2020, August 31). Study Group on Demand and Supply of Medical Workers, 35th Medical Benefits Subcommittee, Reference Material 3: "Physician maldistribution index through medical security plans".)

With the predicted continued increase in rural migration, in addition to solving the issue of unequal distribution of doctors, promoting self-responsibility for one's health and self-medication for minor illnesses will become increasingly vital.

Section 2　Current State of Self-Medication

2-1. The Current State of Self-Medication

The Japanese government has recently shown a more proactive stance towards the promotion of self-medication.

Firstly, as a part of the "Japan Revitalisation Strategy -Japan is Back-" strategy announced on June 14, 2013, "the creation of a system to provide easy access to medical care and promote self-responsibility for health care with self-medication" is mentioned. In addition, it mentions the strategy to "encourage utilization of pharmacies and pharmacists to promote self-medication, making pharmacies a community-based health information center, providing advice on proper use of OTCdrugs, consult and provide information on health-related issues."[17] In the "Japan Revitalization Strategy Revised in 2014 -Japan's challenge for the future-" announced the following year (announced June 24, 2014), the government sets out specific goals to "accelerate the Rx-to-OTC switch (including test kits) in order to promote self-medication."[18] The plan outlined in this strategy to "create a system that incorporates data from other countries and the voices from the industry and consumers in order to quickly conduct reviews of approval applications," led to the discussions taking place in the Evaluation Council which was set up in 2016[18]. The Evaluation Council aims to examine the suitability and necessity of OTC drugs while incorporating the voices of consumers, providing a transparent consideration process that allows for predictability in the development of Rx-to-OTC drugs.

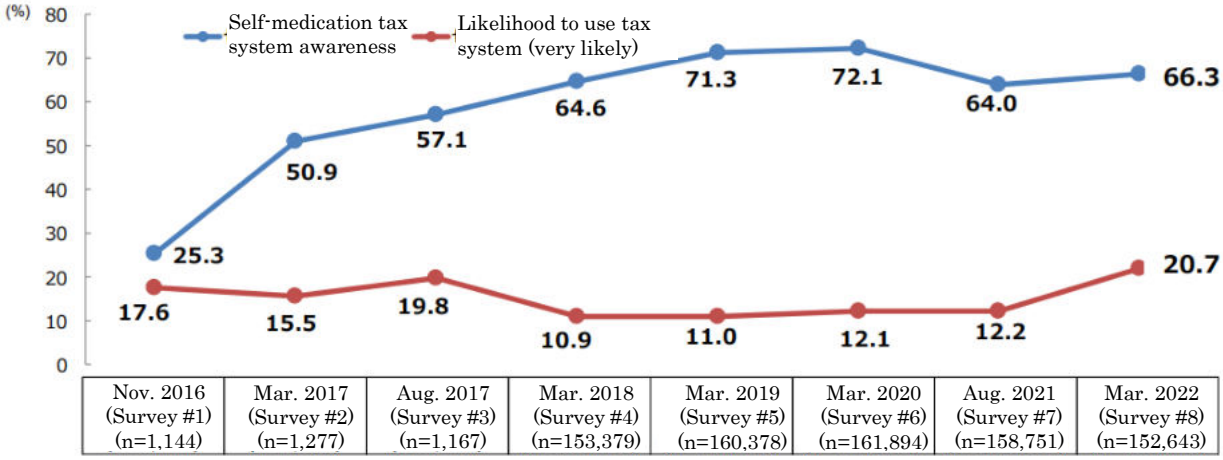
Further, in the "Basic Policy on Economic and Fiscal Management and Reform 2022 For a New Form of Capitalism ～Achieving a Sustainable Economy by Harnessing Processes to Overcome Challenges to Drive Growth～ " (Basic Policy 2022, approved by the Cabinet Office on June 7, 2022), the policy mentions measures to "promote self-medication by considering expanding access to OTC drugs," clearly showing that the promotion of self-medication through OTC drugs and the proactive use of OTC drugs are part of the government's key policies[19].

2-2. The Current State of the Self-Medication Tax System

Although it is a temporary measure, the Japanese government implemented the self-medication tax system, with the goal of promoting change in behavior and awareness of self-medication among its citizens. However, based on data regarding the awareness of and intent to use the self-medication tax system (Figure 4), promotion by the Japanese government and the Japan Self-Medication Industry has slowly improved awareness, but not enough to cause a significant change in behavior[20]. There are three possible reasons for this result. First, the difficulty in submitting a declaration under the self-medication tax system. The current self-medication tax system is antiquated, requiring patients to physically save the purchase receipt and submit the receipt with their tax return, and cannot be used in conjunction with medical expense deductions. Secondly, there are cases where patients who visit a doctor to receive a prescription pay less compared to purchasing OTC drugs. Therefore, the likelihood of patients visiting a

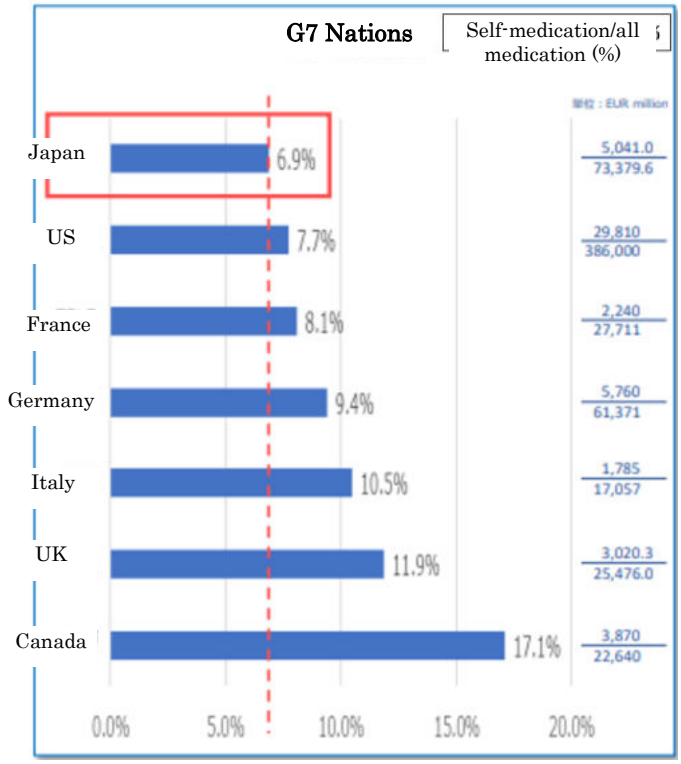
doctor for minor illnesses instead of self-medicating for easily treatable conditions has increased. Thirdly, the number of OTC drugs (therapeutic categories) has not reached a point that allows for the proactive use of self-medication. Japan's universal health care system and free access to hospitals has made it easy to visit a doctor even for minor illnesses, leading to a mere 6.9% of all drugs being OTC, the lowest among G7 nations[21] (Figure 5). In addition, according to research by the Japan Self-Medication Industry, over half responded that they would be more interested in utilizing the tax system, if drugs covered by the system were expanded[22] (Figure 6). Therefore, it can be assumed that increasing the number of OTC drugs applicable under the self-medication tax system is an effective way to promote the switch to self-medication.

Figure 4. Awareness and intent to use of the self-medication tax system



(Source: Japan Federation of Self-Medication Industries, Japan Self-Medication Industry. (2022, September 5). *Seikatsusha 15 man nin kara mieta serufumedikēshon zeisei* [A look at the tax on self-medication from a survey on 150,000 citizens].)

Figure 5. Percentage of OTC medicine as a percentage of all medicine



(Source: Japan Self-Medication Industry. (2023, April 10). *Nihon OTC iyakuhin kyōkai yōbō jikō* [Requests from the Japan Self-Medication Industry].)

Figure 6. Policies to increase use of the self-medication tax system

Note: Survey of those who "want to use" the self-medication tax system out of 160,000 total respondents

	(%)	Expansion to all OTC drugs	Simplified declaration	Removal of lower limit	Don't want to use
Which policies would make you more likely to utilize self-medication tax system?	n=19,524	55.0	20.8	11.8	12.3

(Source: Japan Self-Medication Industry. (2021, February 3). *Serufumedikēshon zeisei 16 man nin chōsa no kekka* [Results from survey regarding the tax system for self-medication on 160,000 people].)

2-3. Current State of OTC Medicine

Some concerns raised at the Evaluation Council regarding Rx-to-OTC switch is part of the reason for the less aggressive push for Rx-to-OTC switch. For example, emergency contraceptive pills have been at the center of the push for Rx-to-OTC switches, with proponents noting that "a woman's desire to prevent unwanted pregnancy is a fundamental reproductive health right, and a basic human right to autonomy," and that "prescribing emergency contraceptives during weekends or nights can be a burden on healthcare facilities." However, members, mostly doctors, argued that the "limited sexual education compared to other nations" and the "difficulty in judging whether to take the pill" are reasons to be cautious about Rx-to-OTC switches for these pills, leading to prolonged discussions.

In the promotion of self-medication, the widespread adoption of OTC medication, which can be purchased easily at pharmacies and drugstores without a prescription is

essential. However, compared to other countries, Japan has not approved many in-demand drugs as over-the-counter drugs. More details will be provided in the following sections, however, drugs such as emergency contraceptives and ED pills, which many patients are reluctant to visit a doctor for, are not available over the counter. This situation makes it inevitable that the adoption of self-medication remains limited.

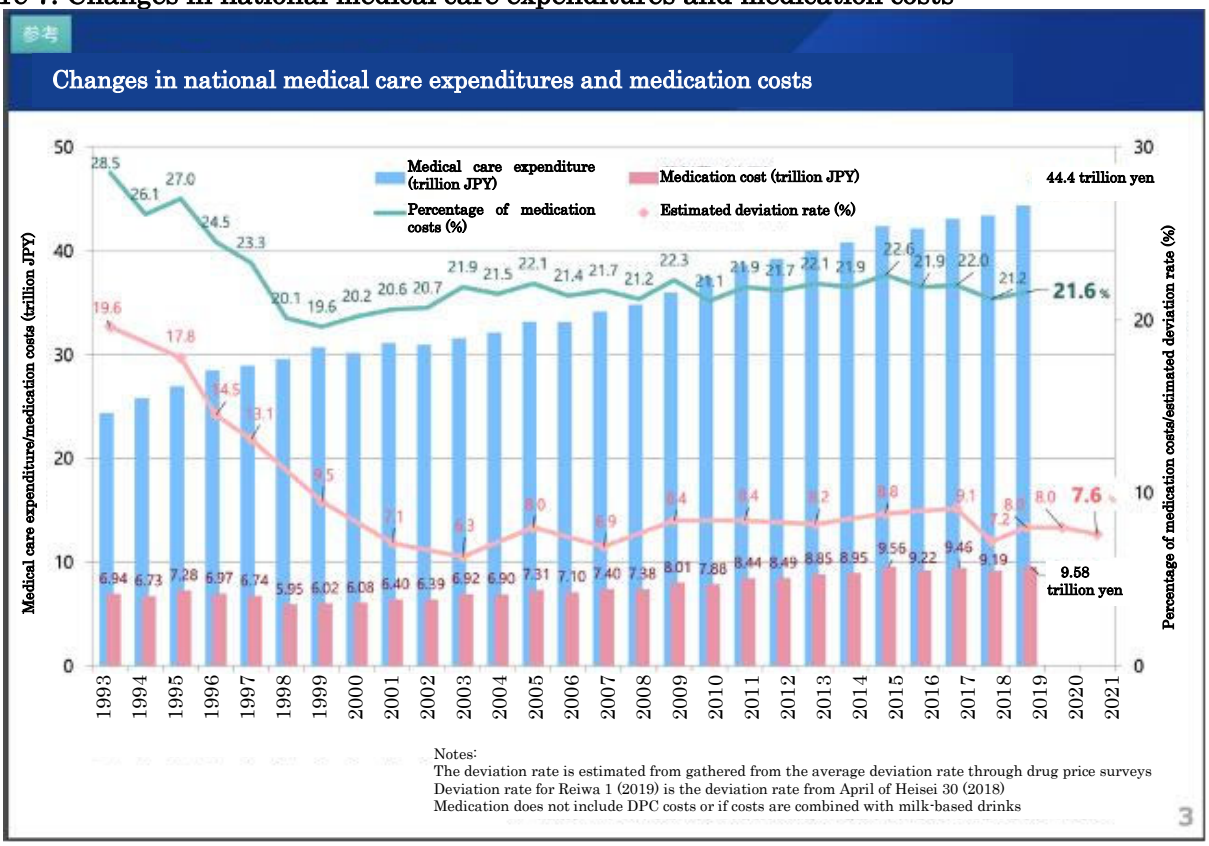
2-4. Main Challenges Covered in this Policy Proposal

Up to this point, we have provided an overview of the current situation in Japan, including the inadequate Access of self-medication and inadequacies in the use of OTC drugs and the Rx-to-OTC switch of drugs. From here, we will cover the various issues that arise from the current situation.

Financial strain of the health insurance system, increasing outpatient consultation times, and difficulty accessing drugs in a timely manner have been raised as issues, and efforts have been made to alleviate these issues.

Regarding financial strain on the health insurance system, there have been efforts to reduce the percentage of drug costs compared to overall medical costs. However, the hesitance to switch from long-listed drugs to generic drugs and OTC drugs can be seen in the effect it has in the percentage spent on drug costs. In 2017, drug costs reached 9.46 trillion yen, making up 22.0% of the total 43.07 trillion medical costs[23] (Figure 7). In order to reduce these costs, the government has been working to switch long-listed drugs (old products that have been listed in the insurance for long time since they were included in the drug price list) to generic drugs where possible and those efforts have had a positive impact. The introduction of the self-medication tax system was also part of the government's efforts to reduce drug costs compared to overall medical costs. According to the MHLW, the switch to OTC medicine is expected to reduce costs by 233 billion yen in existing categories and an additional 88 billion yen in new categories, for a total of 321 billion yen in savings[24].

Figure 7. Changes in national medical care expenditures and medication costs



(Source: Central Social Insurance Medical Council (2022, July 20). *Yakuzaihi tō no nenjisui'i ni tsuite* [Regarding the Changes in Drug Costs]. Ministry of Health, Labour and Welfare.)

In terms of the increasing outpatient consultation times, workstyle reform for doctors will be implemented nationwide starting in April 2024. This workstyle reform was passed in order to alleviate the current situation in the medical industry, where the Japanese medical system heavily relies on doctors working overtime. Currently, the percentage of doctors who surpass the 80 hour per month (960 hours per year) overtime cap for regular employees is approximately 40%. 10% of doctors reach twice that number, with over 1,860 hours of overtime per year. In order to promote healthier working hours while maintaining the current medical care system, the importance of task shifting or task sharing with other healthcare professionals with specialized skills has been raised. The results of these efforts have been notable, and according to a July 2022 survey on hours of overtime at the main building of university hospitals, the number of doctors with 1,860 hours or more of overtime per year was 1,095 [25]. In a July 2023 report by the Japan Municipal Hospital Association, the percentage of doctors with 960 hours of overtime per year was 7.6%, and the percentage of doctors with 1,860 hours or more of overtime declined to 0.4%[26]. In order to continue to improve working conditions for doctors, the use of self-medication to reduce the number of doctor visits and encourage people to take ownership of their own self care, which could help to reduce the risk of severe illnesses. This approach is crucial in alleviating the pressure on doctors and can be streamlined by the use of technology.

Efforts to increase online prescriptions have also been made, as a way to address difficulty accessing drugs in a timely manner. In addition, allowing doctors to privately import drugs in order to prescribe to patients by using the Yakkan Certificate, a

medicine import form, can also be considered an effort to improve a patient's access to drugs. However, these do not meet the needs of the working population who want easier access to drugs, anytime, anywhere, and increased options for drugs that can be purchased without visiting a doctor.

As shown, efforts have been made on various issues that have arisen due to the lack of access for self-medication and the limited spread of OTC drug use and Rx-to-OTC switch. However, it can be said that the government has not solved the core issue that patients face when trying to be responsible for their own health and treating minor illnesses by themselves. This issue can have a severe effect on a patient's health but has been long ignored. That issue is the issue of private importation of drugs.

In this policy proposal, we will cover the issue of private importation of drugs, which is often overlooked when discussing the promotion of self-medication and Rx-to-OTC switch.

Section 3 The State of Privately Imported Drugs in Japan

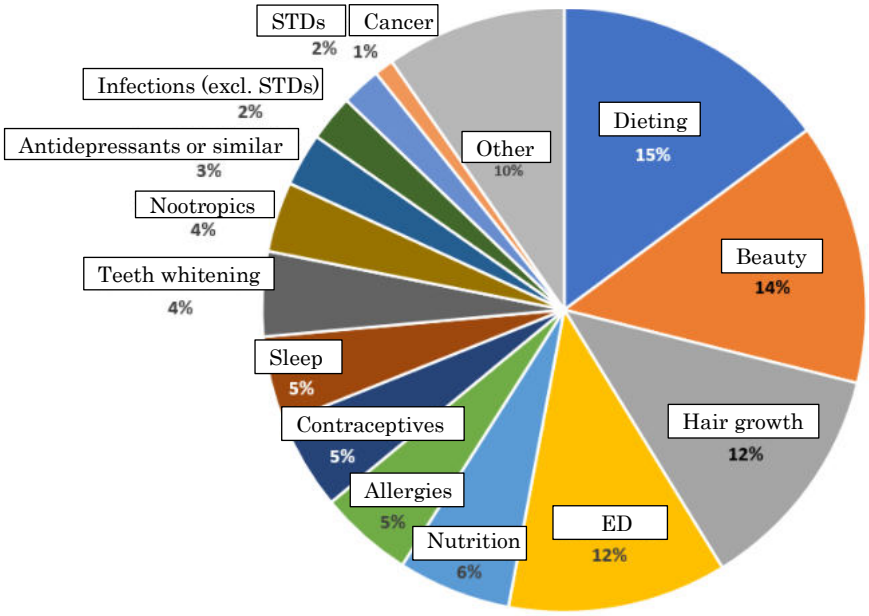
3-1. Types of Drugs that are Privately Imported

While private importation of drugs is legal in Japan, the vast majority of drugs that are imported are off-label drugs. In addition, some of the imported drugs were found to be counterfeit. "Off-label" in this case refers to pharmaceuticals that are approved for use in other countries, but have not been reviewed for quality, effectiveness, and safety under the Japanese Pharmaceutical and Medical Device Act. "Counterfeit drugs" previously referred to pharmaceuticals that are intentionally of fraudulently mislabeled with the brand name or manufacturer, but the latest definition set by the WHO also include low-quality out-of-specification pharmaceuticals, from the perspective of possible public health issues [27].

Looking at the use cases for privately imported drugs, "dieting" and "treating erectile disfunction" rank among the top reasons, with "contraceptives"and "treatment of STDs" also shown as reasons for importation [28] (Figure 8). Online websites ranked as the top means of acquisition for these pills, at 85.5%[28] (Chart 3). Looking at the reasons for purchasing ED pills online, top responses included "the ability to buy the pills anytime and anywhere," "psychological hurdle to visit a doctor," and "inability to purchase the genuine drugs at pharmacies [28](Chart 4). From these results, it can be hypothesized that the reasons for private importation of drugs can be attributed to the lack of an easy way to purchase genuine medicine, which has also led to an increase of consumers who have been affected by counterfeit medicine.

In a survey regarding intention to use websites to privately import drugs, approximately 40% of those who have imported drugs through these sites had a negative view towards them. Despite this, 43% responded that they will continue to use the websites "while recognizing the risks," revealing that many consumers feel a hurdle financially and psychologically when visiting a doctor for prescriptions, leading many to resort to private importation [29] (Figure 9).

Figure 8. Use cases for privately imported drugs



(Source: Ohyanagi, K. (2021, December 23). *Iyakuhin (zenpan) no kojin yunyū jittai chōsa* [Fact-finding Survey on Privately Imported Drugs].)
Chart was created using data from the *Iyakuhin (zenpan) no kojin yunyū jittai chōsa* [Fact-finding Survey on Privately Imported Drugs].

Chart 3. Survey on means of acquisition for privately imported drugs

	n	%
Means of acquisition for privately imported drugs (n=1,043, multiple answers allowed		
1. Purchased through internet, phone or fax from Japan	892	85.5
2. Purchased overseas and personally brought to Japan	143	13.7
3. Purchased overseas and shipped to personal address in Japan	56	5.4
4. Other	44	4.2

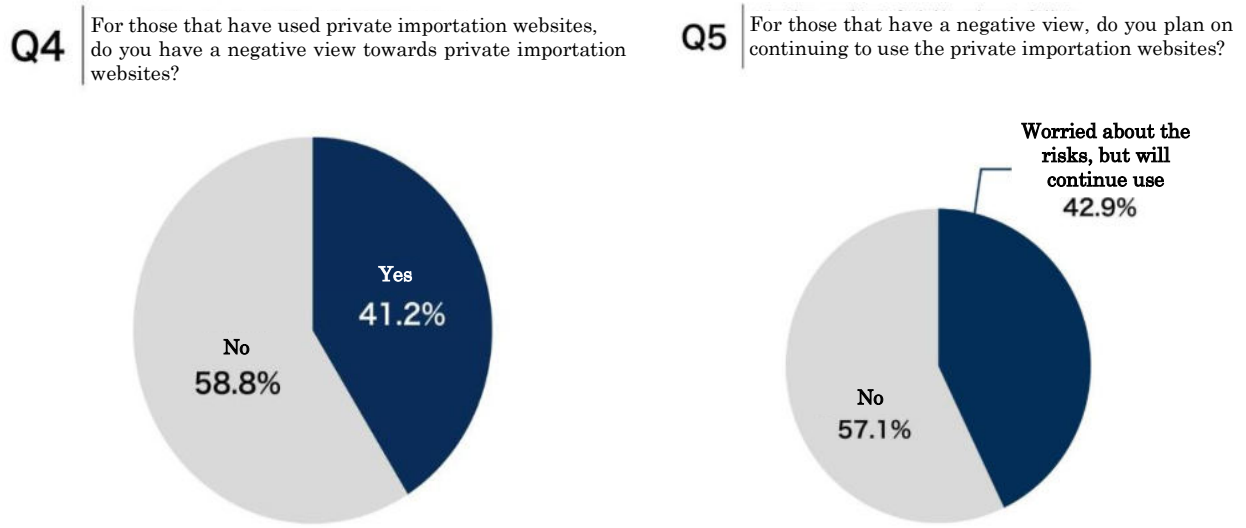
(Source: Ohyanagi, K. (2021, December 23).*Kojiin yunyū sareru raifusutairu doraggu no jittai ni kansuru kenkyu -omoni biyou kanrenyaku oyobi noukinou chouseiyaku ni tsuite – buntan kenkyū houkokusho* *Iyakuhin (zenpan) no kojin yunyū jittai chōsa* [Research on the State of Privately Imported Lifestyle Drugs -Mostly Beauty-Related Drugs and Nootropics- Shared Research Report "Fact-finding Survey on Privately Imported Drugs"].)

Chart 4. Reasons for private importation of drugs

	n	%
Reasons for private importation of drugs (multiple answers allowed)		
1. Affordability	534	51.2
2. Ability to easily order online	537	51.5
3. Due to hassle of going to a hospital, clinic or pharmacy	203	19.5
4. Privacy reasons	166	15.9
5. Cannot purchase in Japanese pharmacies	298	28.6
6. For effects that can't be obtained from drugs on sale in Japan	173	16.6
7. Cannot trust getting proper treatment at a hospital or clinic	50	4.8
8. In order to continue treatment overseas	20	1.9
9. Other	40	3.8

(Source: Ohyanagi, K. (2021, December 23).*Kojiin yunyū sareru raifusutairu doraggu no jittai ni kansuru kenkyu -omoni biyou kanrenyaku oyobi noukinou chouseiyaku ni tsuite – buntan kenkyū houkokusho* *Iyakuhin (zenpan) no kojin yunyū jittai chōsa* [Research on the State of Privately Imported Lifestyle Drugs -Mostly Beauty-Related Drugs and Nootropics- Shared Research Report "Fact-finding Survey on Privately Imported Drugs"].)

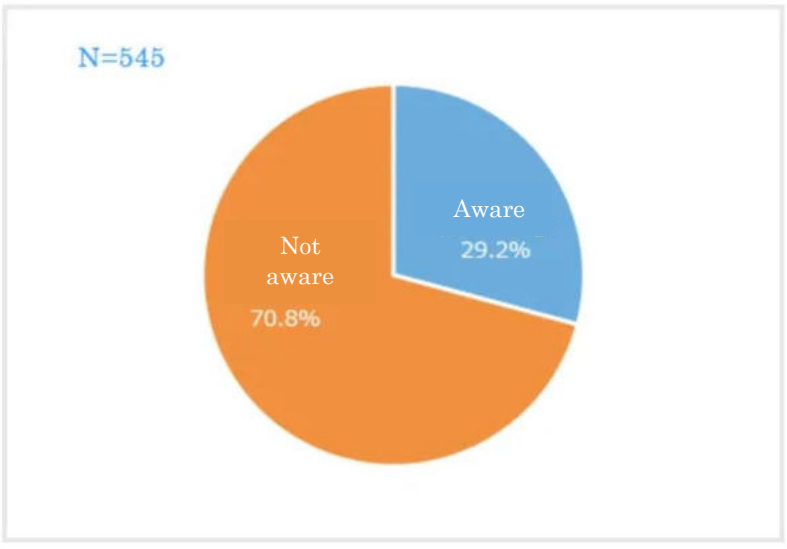
Figure 9. Consumer sentiment towards private importation websites



(Source: Inui, Y. (2022, October 2). *Iyakuhin no kojin yunyū saito, 41% ga negatibu na inshō wo idaku* [41% have a negative impression of private importation sites for medication]. Actually, inc.)

In addition, it is likely that the lack of awareness of the existence of counterfeit drugs among those privately importing drugs, has also led to increased health risks from counterfeit drugs. In a survey of 545 men in their 40s living in the Kanto area regarding erectile dysfunction and the use of pills to treat erectile dysfunction, less than 30% responded that they knew that over half of erectile dysfunction pills were found to be counterfeit and the potential health risks associated with those counterfeit drugs [30] (Figure 10).

Figure 10. Awareness that over half of ED pills purchased online are counterfeit



(Source: Takekoshi, A. (n.d.). *ED chiryōyaku ni tsuite 40 dai dansei 545 nin ni kītemita* [Asking 545 men in their forties about ED medication]. Hamatsuchō Dai'ichi Clinic.)

As the data shows, in addition to the number of consumers unaware of the possibility of receiving counterfeit drugs through private importation, there are consumers aware of the risk, but are faced with no other options to purchase those drugs without private importing. From a consumer protection standpoint, there is a need to raise awareness on the risks of private importation through the internet and to increase avenues to easily purchase genuine drugs anytime, anywhere.

3-2. Examples of Health Issues Caused by Private Imports and Counterfeit Drugs

There have been many reports of health issues due to the use of off-label drugs. As an example, a pregnant woman who privately imported oral abortion pillslabeled as "made in India" suffered from heavy bleeding, convulsions, and stomach pain and was later hospitalized [31]. There have been other reports of health issues from the use of counterfeit drugs. A few hours after a man in his 40s took 50mg of a privately imported counterfeit Cialis, the man suffered from convulsions and impaired consciousness, and was taken to the hospital[32].

In addition, in reports related to drugs containing omeprazole, two out of 28 imported samples (7.1%) from Thailand and Taiwan were found to have insufficient active ingredients [33]. In the same report, out of the samples of omeprazole purchased locally in Cambodia in 2010, 50% were did not pass quality tests. Drugs made by the same manufacturer are available on websites selling drugs for private importation, meaning there is a high possibility that those low-quality drugs are being imported to Japan through those sites [33].

Further, a research study was conducted between March 2016 and August 2016 on counterfeit ED drugs, led by the four manufacturers of these drugs (Pfizer, Bayer Yakuhin, Eli Lilly Japan, and Nippon Shinyaku). Viagra, Cialis, and Levitra were imported from these websites under the guise of private importation, and 40% of the purchased drugs were found to be counterfeit[34]. It is clear from this study that the circulation of counterfeit drugs within the country is increasing.

Consumers are not the only group affected by the circulation of counterfeit drugs. For example, there is a possibility that pharmaceutical companies see reduced sales or reduced sales of drugs with the same chemical substances, from reputational damage caused by consumers purchasing counterfeit drugs. By extension, it is possible that a drop in sales could lead to a reduction in R&D funds and inhibit the development of new pharmaceuticals.

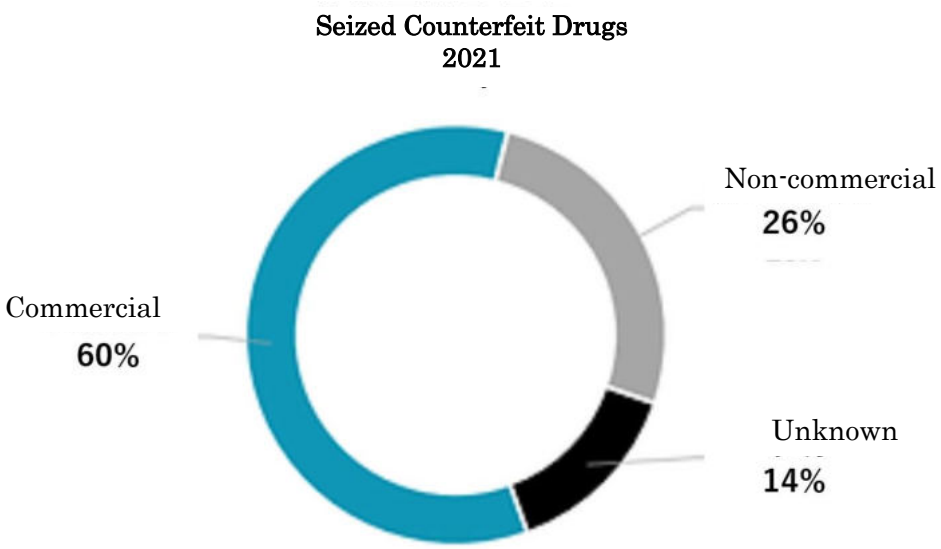
With the purchasing of drugs online becoming more common, it is predicted that private importation of drugs will continue to increase, and in turn, there is a possibility that health issues associated with counterfeit drugs will also increase. While Japan has a "Relief System for Sufferers from Adverse Drug Reactions, etc." for approved drugs, any adverse reactions for privately imported drugs are not eligible. Therefore, currently there are no safety nets related to any health issues caused by privately imported drugs.

According to a 2002 study by the Pharmaceutical Security Institute (PSI), founded in Washington, D.C. by 14 major pharmaceutical companies, approximately 60% of counterfeit drug related crimes involve criminal organizations [35] (Figure 11). In

addition, the area of diseases most often targeted for the creation of counterfeit drugs were genito-urinary drugs [35] (Figure 12).

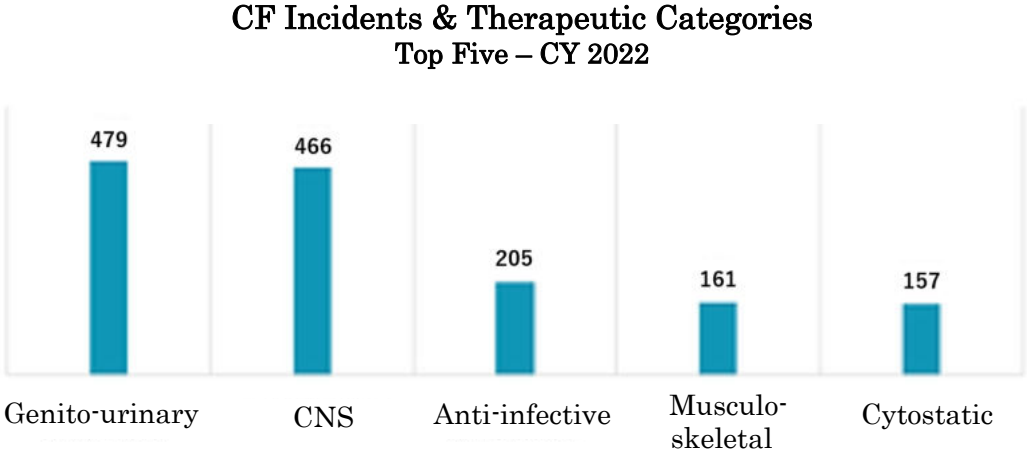
Taking these points into consideration, the proliferation of counterfeit drugs has the possibility of becoming a widespread social issue, making quick action to deal with these counterfeit drugs crucial.

Figure 11. Analysis of seized counterfeit drugs



(Source: Pharmaceutical Security Institute. (n.d.). *Therapeutic Categories.* Retrieved 2023, July 28.)

Figure 12. Counterfeit drug cases by area of disease



(Source: Pharmaceutical Security Institute. (n.d.). *Therapeutic Categories.* Retrieved 2023, July 28.)

Section 4　The Current State of Private Importation and Possible Solutions

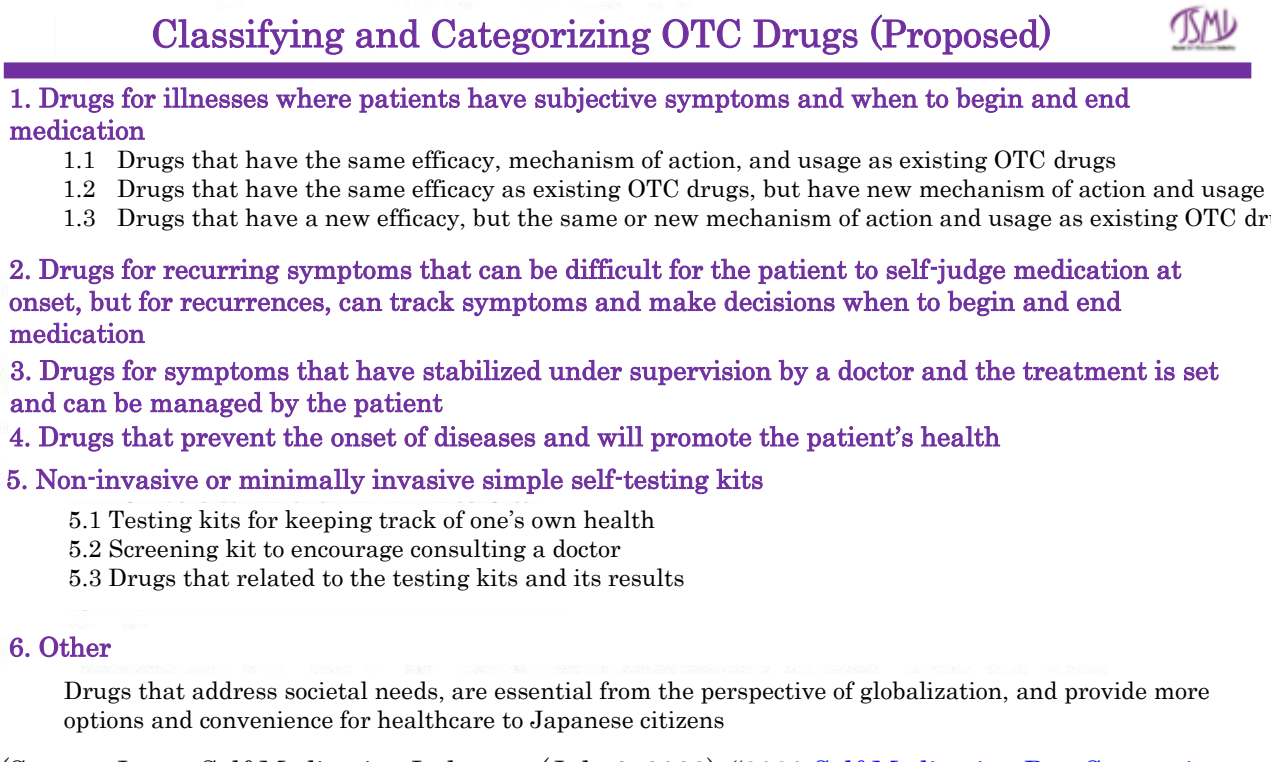
As outlined above, health risks caused by private importation of drugs are becoming a major issue. As such, various stakeholders have made numerous efforts to curb the risks associated with private importation. The MHLW has created a website called "Ayashii Yakubutsu Renraku Net," which provides information on the dangers of counterfeit drugs, websites selling counterfeit drugs, and precautions to take when purchasing genuine drugs. Pharmaceutical manufacturers such as Chugai Pharmaceutical and Astellas Pharma have also set up internal committees to combat counterfeit drugs and have raised awareness on the dangers of counterfeit drugs at seminars across the world, proactively working to curb the importation and use of counterfeit drugs.

However, damage caused by counterfeit drugs has reached 363.5 million yen[36], and efforts have yet to curb the import of those drugs by a significant margin. Effort to raise awareness alone is not enough to stop the counterfeit, since consumers desire easily accessible channel to drugs. In order to effectively reduce the damage counterfeit drug can cause, we need to address the root cause directly, that is to increase drug availability through genuine channels..

In this policy proposal, we raise Rx-to-OTC switch of drugs as one way to curb the damages incurred from counterfeit drugs. The Japan Self-Medication Industry has set out the following five guidelines for drugs that should be considered for Rx-to-OTC switch[37] (Figure 13).

1. Drugs for illnesses where patients have subjective symptoms and can self-judge when to begin and end medication
2. Drugs for recurring symptoms that can be difficult for the patient to self-judge medication at onset, but for recurrences, can track symptoms and make decisions on when to begin and end medication
3. Drugs for symptoms that have stabilized under supervision by a doctor and the treatment is set and can be managed by the patient
4. Drugs that prevent the onset of diseases and will promote the patient's health
5. Non-invasive or minimally invasive, simple self-testing kits

Figure 13. Classifying and Categorizing OTC Drugs



(Source: Japan Self-Medication Industry. (July 8, 2022), "2022 Self-Medication Day Symposium Report".)

In addition, comparing Japan with other countries, drugs such as omeprazole or levonorgestrel, used in emergency contraceptive pills, have yet to be approved in Japan, and are key drugs that should be considered for Rx-to-OTC switch. It is important to promote the Rx-to-OTC switch for drugs such as these, providing easier access to genuine drugs, and protecting patients from off-label and counterfeit drugs.

However, while Rx-to-OTC switch of drugs is effective in preventing the circulation of counterfeit drugs, those efforts alone will not prevent all private importation of drugs. The proactive use of technology is also key in preventing the circulation of counterfeit drugs. With recent advancements in technology, it is becoming possible to track purchases made online. Further, manufacturers such as Chugai Pharmaceutical and Astellas Pharma have implemented technologies to prevent the circulation of counterfeit drugs. For example, Astellas Pharma has implemented technology to track circulation of its drugs outside of genuine distribution channels through monitoring of online pharmacies and marketplaces and has implemented technologies for its frequently counterfeited drugs to determine the authenticity of those drugs[38]. Further, in a report by KPMG, the possible use of blockchain to curb the proliferation of counterfeit drugs is being considered [39]. The use of the latest technologies like these is essential to create an environment where patients are properly provided with genuine drugs.

Section 5　Japan's "Switch Lag"

The previous section provided an overview of the problem of private import and counterfeit drugs while highlighting the importance of promoting the Rx-to-OTC switch as a potential solution. This section will discuss the current state of the Rx-to-OTC switch and the challenges when implementing it.

5-1. The Current State of Switch Lag

According to the MHLW's "Regarding the Submission of Requested Substances for Potential Rx-to-OTC Switch Medications," as of July 28, 2023, of the substances that were requested for Rx-to-OTC Switch between 2016 and 2021, the results of consideration were not released for 10 substances[40]. Many of these are sold over the counter abroad, but require a prescription in Japan, and there are cases of private importation in order to obtain them. Table 5 below shows, categorized by substance, the year the Rx-to-OTC Switch was approved in Japan, the first country to approve the switch (year, country), and the years between the first instance of approval and Japan's[41]. It is clear from Table 5 the delay for Japan in Rx-to-OTC switch compared to other countries. In the case of emergency contraceptives (levonorgestrel), there is a gap of over 20 years between France and Mexico - the first countries to make the switch (approved in 1999) - and Japan. Moreover, emergency contraception is approved for Rx-to-OTC switch by nearly 30 countries. (The conclusions and a summary of the opinions from the Evaluation Council meeting held on June 27, 2023, during the writing of this report, will be submitted to the Pharmaceutical Affairs and Food Sanitation Council, which showed a significant advancement toward the approval of the Rx-to-OTC Switch).

Table 4. List of Rx-to-OTC Switch Lag

Medicinal Effect	Substance	Year approved in Japan	First instance of switch		Switch Lag	Number of Countries approved (out of 40)	Country that developed the drug
			Year	Country			
PPI	Omeprazole	Not approved	1999	Sweden	>21 Years	30	Sweden
	Lansoprazole	Not approved	2004	Sweden	>16 Years	6	Japan
	Rabeprazole	Not approved	2010	Australia	>10 Years	2	Japan
Anti-migraine	Sumatriptan	Not approved	2006	United Kingdom	>14 Years	5	United Kingdom
	Zolmitriptan	Not approved	2009	New Zealand	>11 Years	3	United Kingdom
	Rizatriptan	Not approved	2010	New Zealand	>10 Years	2	United States
	Naratriptan	Not approved	2006	Germany	>14 Years	1	United Kingdom
Emergency contraceptive	Levonorgestrel	Not approved	1999	France Mexico	>21 Years	29	France
Anti-herpesvirus	Aciclovir	2007	1992	Germany Finland New Zealand	15 years	35	United States
Hair growth	Minoxidil	1999	1993	Denmark	6 years	38	United States
Vaginal Candidiasis	Miconazole	2008	1983	France	25 years	19	Belgium
	Clotrimazole	2011	1983	France	28 years	33	Germany
Smoking cessation	Nicotine gum	2001	1988	Australia	13 years	37	Sweden
Rhinitis steroid	Fluticasone	2019	2002	United Kingdom Ireland	17 years	19	United Kingdom
Anti-allergic	Fexofenadine	2012	2007	Bulgaria	5 years	9	United States
	Loratadine	2017	1988	Canada	29 years	35	United States

(Source: Japan Self-Medication Industry. (2020, February 13). *Iryō'yō iyakuhin kara ippanyō iyakuhin e no tenyō (suicchi OTC ka) no sokushin* [Promoting Prescription-to-Nonprescription (Rx-to-OTC) Switches]. Cabinet Office, Government of Japan.)

This difference in time between the Rx-to-OTC Switch overseas and in Japan is referred to as "switch lag". Because of this switch lag, Japan has significantly less options for self-medication compared to other countries.

5-2. Reasons for Switch Lag

What is the reason for switch lag? There are 3 main reasons that account for it. First, there is no goal or roadmap set by the government for Rx-to-OTC drugs. In the "Japan Revitalization Strategy" released in 2013, promotion of access to self-medication was raised as one of the important measures and described a plan for 2014 to promptly evaluate requests from companies while referencing overseas data and respond to more varied opinions from the industry and consumers[17]. Though Japan seems to be moving in the direction of supporting OTC switches, there are no clear goals such as "*x* number of medications are to be switched to OTC in *y* number of years", nor has a roadmap to complete those goals been considered.

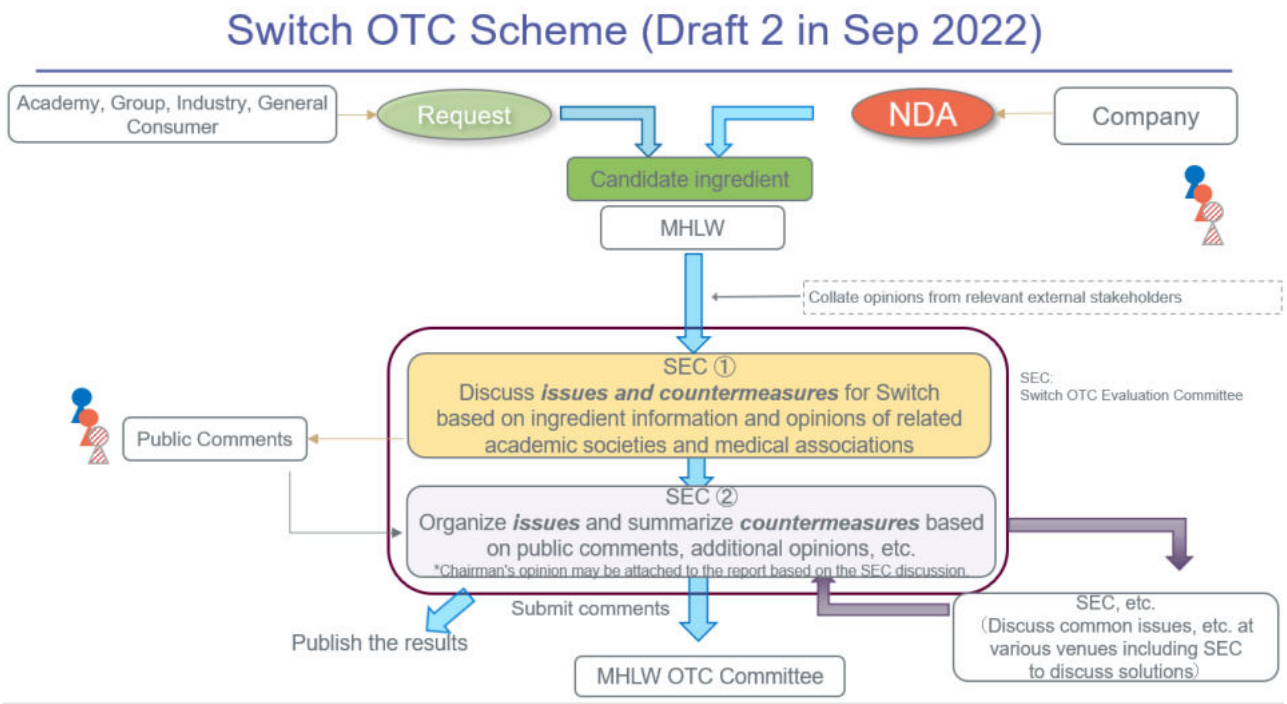
As a prior example, there was a Cabinet decision in June 2007 to increase the share of generic medicine to over 30% by 2012, in order to reduce medical expenses, but this goal was not achieved. However, the Comprehensive Reform of Social Security and Tax (Cabinet Office decision made on February 17, 2012), stated a plan to create a roadmap for generic medicine, utilize the medical service fee system, provide information to patients, change the prescription format, improve the quality of healthcare professionals to increase credibility, and other efforts to thoroughly promote the use of generic medicine, and they established the Roadmap for Further Promotion of Generic Medicine Use in April 2013. Through these efforts, in the 3rd quarter of 2021 (October to December 2021), the share of generic medicine reached 79.3% (from a preliminary report)[42]. It is clear that setting goals and roadmaps are important.

Second, the points discussed at the evaluation meeting are unfocused. Taking the discussion on switching emergency contraceptives to OTC as an example, several topics were raised and heavily discussed, such as "sexual education in Japan is behind compared to the West, and users of the contraceptives do not have enough knowledge," "if pharmacists are to sell it, they need to be equipped with specialized knowledge in reproduction and birth control," and "Japanese citizens have a low awareness of emergency contraceptives." The purpose of the evaluation meeting is stated - to evaluate the suitability and necessity of switching the medication to OTC, and to work to solve the challenges of the switch and their solutions. However, the concept of the proper use of drugs was broadly interpreted and led to points unrelated to the purpose of the meeting, and some point out that this hindered the progression of the discussion. In the second evaluation meeting held in July 2017, a committee member stated that they do not think Japan can make the drug publicly available until sexual education reaches the level of the United States and Europe, extending the topic of discussion to the state of sexual education in Japan. Organizing the opinions raised takes time due to the discussions straying into areas the MHLW does not have authority over, and they evaluate the approval of OTC drugs on criteria other than suitability and necessity.

Third, there are no deadlines for the approval process and evaluation meetings. Emergency contraception has been discussed at the meetings for a total of 6 years. In addition to the unfocused discussions, the cautiousness of the Japan Medical Association's representatives toward the Rx-to-OTC switch is also a contributor to the prolonged discussions. Using emergency contraceptives as an example, the April 28, 2022 issue of the Nihon Keizai Shimbun criticizes the healthcare industry's cautious stance and that the Japan Medical Association representative hindered discussion by stating the documents were too long to read[43].

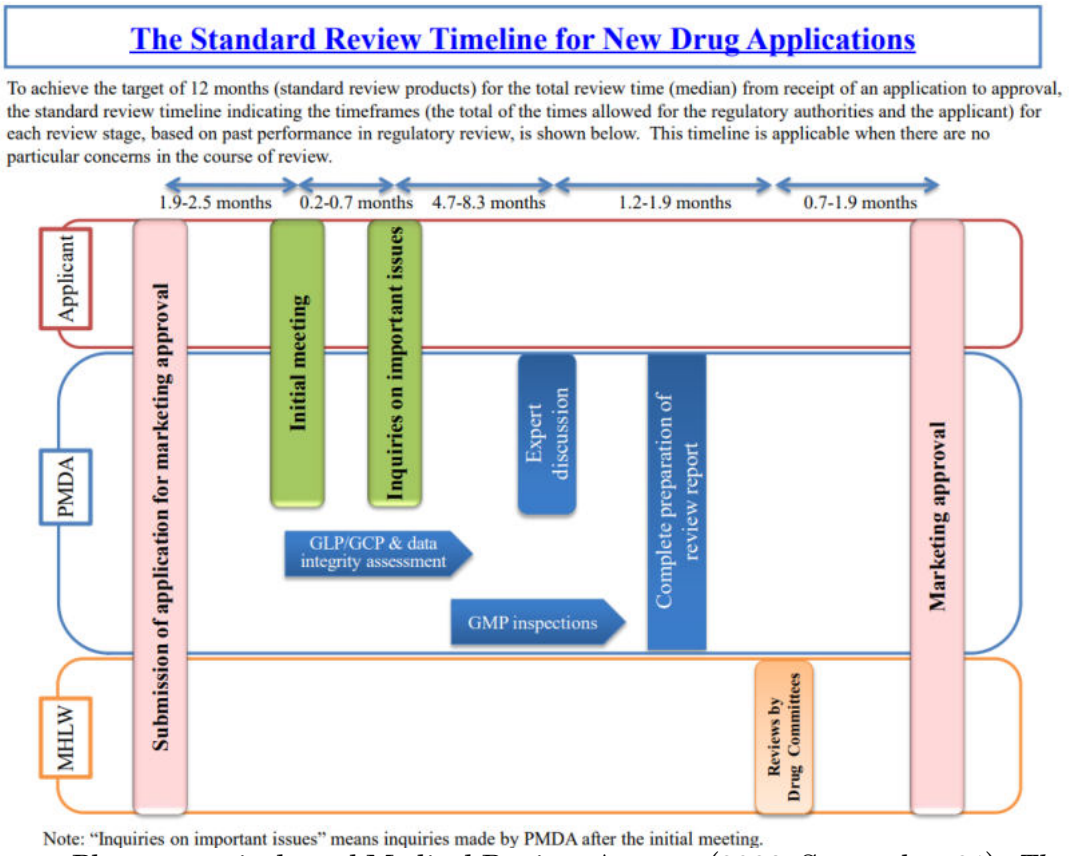
The Regulatory Reform Implementation Plan, decided on by the Cabinet Office on July 17, 2020, states that the role of the Evaluation Council is to organize the challenges and issues of the requested substances for Rx-to-OTC Switch, and to present them to the Pharmaceutical Affairs and Food Sanitation Council, not to decide whether the substance should be switched to OTC. It also states that the requirement for the evaluation meeting to reach a unanimous vote should be reconsidered, and instead, if there are differing opinions and a consensus cannot be reached, the opinions should be listed and presented to the Pharmaceutical Affairs and Food Sanitation Council. This led to the removal of the unanimous vote rule and reconsideration of the system of the meetings. While thorough discussions are necessary when discussing medicine concerning human lives, deciding on what points to discuss, having criteria to finalize the discussion, and setting an evaluation period are all vital to minimize switch lag. Japan's approval scheme for over-the-counter (OTC) versions of prescription drugs ("switch OTC drugs") involves a review at the Assessment and Review Board, followed by deliberations of the Committee on Guidance-Mandatory Drugs and Non-prescription Drugs, a unit of the Pharmaceutical Affairs and Food Sanitation Council, to make a decision on whether to approve a specific product[44] (Figure 14). In contrast, the review process for the approval of new drugs, in which the evaluation of efficacy and safety starts from scratch, is completed approximately 1 year after pharmaceutical companies submit new drug applications. Thus, switch OTC drugs, which have a certain amount of efficacy and safety data accumulated, need to successfully pass the Assessment and Review Board and the public comments process before they can undergo deliberations for approval, meaning that the review process for switch OTC drugs involves more steps than those for new drugs[44,45] (Figures 14 and 15). Proposals that consider these issues will be described in detail in Section 7.

Figure 14. Standard flow of the review process for switch OTC drugs application



(Source: Ministry of Health, Labour and Welfare. (2022, December 26). 23rd Evaluation Meeting on Rx-to-OTC Switch. file 1: *How to discuss in the SECs*)

Figure 15. Standard flow of the review process for new drugs application



(Source: Pharmaceuticals and Medical Devices Agency. (2023, September 21). *The Standard Review Timeline for New Drug Applications.*)

5-3. Other Challenges for the Rx-to-OTC Switch

There are several challenges that are likely to surface as the promotion of OTC drugs continues. First, evidence relating to OTC drugs is not adequately shared or compiled in Japan, due to the lack of opportunity to discuss the promotion of it, causing Japan's stance on using OTC drugs to remain unclear. With generic drugs, the Japanese Society of Generic and Biosimilar Medicines (made up of those involved in the pharmaceutical industry) was able to introduce the widespread use of generic drugs by creating opportunities for various stakeholders to discuss and gather evidence for the promotion of generic drugs.

Second, there is a possibility that drugs with contraindications would be prescribed, because the current process for treatment and prescription does not consider OTC drugs. Lastly, as a policy to promote the Rx-to-OTC switch, the government has implemented the self-medication tax system, however, the system for declaration is outdated (requiring calculation of the total amount from receipts of applicable drugs when filing for tax returns) and highly inconvenient, adding to the difficulty of normalizing self-medication among Japanese citizens.

Section 6　The Benefits of Self-Medication

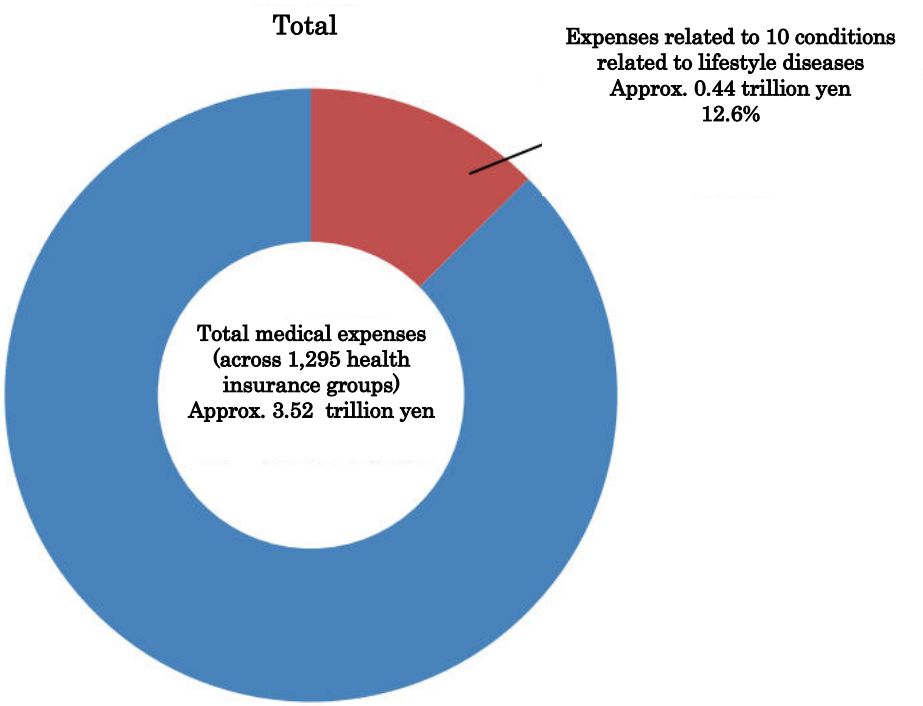
In this section, we will focus on medicines that are available in Japan through private importation, but not yet approved by the government as Rx-to-OTC Switch drugs, and the possible benefits of their approval as OTC drugs (and resolve switch lag), along with case studies of other countries.

6-1. Drugs for Treatment of Lifestyle Diseases

Out of the 3.52 trillion yen in total medical expenses (across 1,295 health insurance groups), the expenses related to 10 conditions related to lifestyle diseases are 0.44 trillion yen, or 12.6% of total expenses [46] (Figure 16).

Yokohama City University Associate Professor Ataru Igarashi's report (MHLW Administrative Research Grant (MHLW Special Research) Summary/Shared Research Report (2021), Research on the Self-Medication Tax System's Effect on Medical Cost Optimization), the share of OTC drugs versus the total sales of OTC drugs and prescriptions was 7.1%[47]. In addition, for the drugs to treat hypertension among the drugs for lifestyle-related diseases, Associate Professor Igarashi presented the estimated impact of switching of the drugs for hypertension to over-the-counter drugs on medical cost reduction in the first council of experts on self-medication, which was held on February 3, 2021. According to this presentation, the potentially reduced medical cost is estimated to be approximately 79.6 billion yen if patients with hypertension who are manageable with over-the-counter drugs use self-medication [24] (Figure 6).

Figure 16. Medical expenses related to 10 lifestyle disease conditions as a percentage of total medical costs



(Source: National Federation of Health Insurance Societies. (2021, June). *Reiwa gan nen do seikatsu shūkan kanren shikkan iryōhi ni kansuru chōsa* [Investigation on Medical Expenses of Lifestyle-Related Diseases 2019].)

Chart 6. Medical cost reduction effect by switching to OTC drugs

What is the effect of reducing medical costs by switching to OTC drugs?
(Summary of results)

Existing Fields				New Areas			
Disease	People (A, 10,000)	Medical fee (B, yen)	Total (billion yen)	Disease	People (A, 10,000)	Medical fee (B, yen)	Total (billion yen)
cold	560.0	7,200	403.2	Muscle relaxants for back and shoulder pain	13.0	10,486	13.6
headache	126.7	5,300	67.2	irritable bowel syndrome	16.3	7,617	12.4
lower back painshoulder pain	92.0	8,830	81.3	High blood pressure	985.6	8,085	796.9
constipation	234.5	5,749	134.8	migraine headache	49.3	10,655	52.5
heartburn	287.8	7,457	214.6	PPI such as heartburn	10.3	8,745	9.0
nasal inflammation	1668.7	8,561	1,428.7				
total ·			2,329.7				884.3

Existing Fields 2,330billion yen · New Areas 880 billion yen, total 3,210 billion yen

(Source: Ataru Igarashi. 1st Expert Panel on the Promotion of Self-Medication, open document. (2021, February 3). *Potential Medical Cost Reduction Effects of OTC Drugs.*)※Translation by corporate author

6-2. ED Pills

Recent studies have shown that men with erectile dysfunction (ED) have a 2.5 times higher chance of cardiovascular diseases such as strokes and heart attacks, compared to those not diagnosed with ED [48]. In addition, in a study of 197 patients with high risk of cardiovascular diseases such as coronary heart disease or strokes, over 80% had been diagnosed with ED an average of three years before their first cardiovascular event; with 79.2% diagnosed with coronary heart disease, 29.4% with myocardial infarction, 9.1% with strokes, and 78.2% with high blood pressure[49]. Those with organic ED have a risk of diabetes, arteriosclerosis, or high blood pressure, and those with psychogenic ED face the risk of mental health issues such as depression, if untreated[50]. From this data, it can be said that the early detection and early treatment of ED can help reduce the risk of myocardial infarctions [48]. In addition, the Rx-to-OTC switch of ED drugs will allow for screening and consulting from a pharmacist at the time of purchase, which could lead to doctor visit recommendations that would help with early discovery of serious illnesses.

In addition, the social cost (the sum of private costs and external cost) for the treatment of these diseases was calculated by e-solutions, inc. and national research

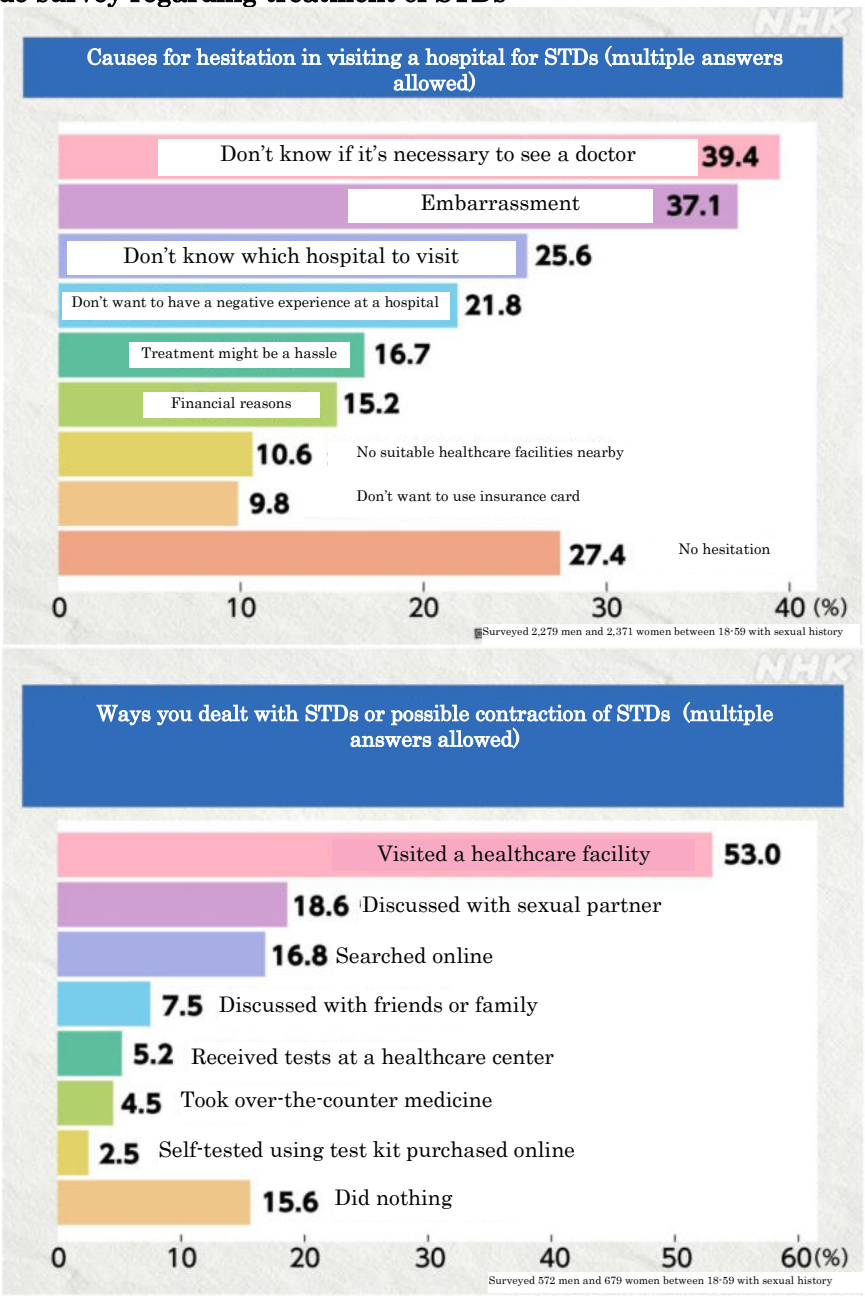
institutes. Results showed that early discovery of strokes could help reduce social costs by 0.69 to 0.89 trillion yen, and early discovery of cardiovascular diseases could reduce costs by 0.38 to 1 trillion yen[51].

In a public assessment report regarding the Rx-to-OTC switch of ED drugs in UK, it was concluded that it reduces health risks associated with the unintentional purchasing and use of counterfeit drugs that are sold online. It is likely that this will also apply to those patients suffering from ED in Japan [52].

6-3. STD Testing Kits

In an attitude survey regarding the treatment of STDs, 40% of respondents noted hesitation to see a doctor due to shame or embarrassment[53] (Figure 17). This has led to only about half of patients who contracted an STD or feared they contracted an STD visiting a doctor or receiving a test[53] (Figure 17). The rise in cases of STDs in Japan can be attributed to this hesitation in receiving tests and treatment. The spread of STDs is a worldwide issue, and countries have implemented various efforts to curb the spread. For example, in the UK, the government has partnered with a NPO to distribute STD testing kits to those that request them. This ease of access to testing kits should also be implemented in Japan with OTC testing kits, allowing tests without the need to visit a doctor, so those who have contracted STDs can quickly receive proper tests and proper treatments.

Figure 17. Attitude survey regarding treatment of STDs



(Source: NHK. (2023, January 24). *Baidoku kyūzō naze? Sei kansenshō no gokai to keishi* [Why the sudden increase in Syphilis? The misconception and disregard of sexually transmitted diseases].

6-4. Doctor Visit Recommendations by Health Insurance-Approved Pharmacies and Related Challenges

Below, we will cover cases where pharmacists recommended patients to see a doctor, and the role health-insurance approved pharmacies and pharmacists should play in the promotion of self-medication, as well as possible challenges. These case studies were provided by Yuya Iijima, Director, Ueda Yakuzaishikai; President, Iijima Co., Ltd.; Pharmacist, Iijima Pharmacy. Mr. Iijima formerly directed the pharmacy, academic and training departments of the Ueda Yakuzaishikai, and headed the Japan-Australia Academic Exchange Committee. He has also presented at working groups regarding

the work of pharmacists and their functions, in addition to presentations at government committees and study groups.

6-4-1. Case Studies

Case 1

Patient information:
Female, 30s, visited Iijima Pharmacy with stomach pains, first visit
Chief complaint and treatment:
The patient visited Iijima Pharmacy early in the morning with stomach pain, looking to purchase OTC stomach medicine. In the consultation prior to purchasing the medicine, Mr. Iijima consulted with the patient on the amount of pain, timing and location of the pain, the patient's diet, bowel movements, concomitant drugs, and whether the patient had nausea. From this consultation, he suspected a gastric ulcer and recommended seeing a doctor. Since a gastric ulcer was suspected, Mr. Iijima recommended a hospital that allowed same-day gastroscopic examinations. He also shared information about the patient's condition and request for the gastroscopic examination with the hospital and provided instructions to the patient on how to prepare for the examination.
Results:
Mr. Iijima was informed that the patient was diagnosed with a gastic ulcer following tests and that she was hospitalized. Due to the early visit to the hospital, the patient was able to receive proper care before the condition worsened and became a gastrointestinal perforation.

Case 2

Patient information:
Female, 80s, primary care patient, visited with stomach pains and fatigue
Chief complaint and treatment:
Patient visited Iijima Pharmacy with a stomachache and fatigue. After consultation regarding the symptoms, Mr. Iijima suspected an aortic aneurysm following additional information on the patient's pre-existing conditions (high blood pressure), concomitant drugs, medical history, family medical history, stress (anxiety), lifestyle (diet and exercise), ADL, cognitive function, and living environment. There, a recommendation was made to see a doctor.
Results:
An aortic aneurysm was found, and the patient was able to receive surgery.

Case 3

Patient information:
Male, teenager, visited Iijima pharmacy with swollen eye, looking to purchase eye drops, first visit.

Chief complaint and treatment:
Visited Iijima Pharmacy to purchase eye drops. A clinical examination found inflammation, swelling and discharge in the eye, and was recommended to see a doctor, rather than prescribing OTC drugs. Mr. Iijima recommended a nearby doctor and the patient received an examination.
Results:
The hospital prescribed levofloxacin and fluorometholone eye drops. No information was provided following prescription.

6-4-2. Role of Health-Insurance Approved Pharmacies and Pharmacists and Challenges in Filling Those Roles

As seen in the cases above, it is possible for a pharmacist to consult with the patient and recommend a doctor visit. According to Mr. Iijima, getting recommendations from a pharmacist to visit a doctor is a regular occurrence in Ueda City, where the pharmacy is located. Within the cases provided by Mr. Iiijma, there were multiple cases where the recommendation to visit a doctor allowed early discovery of an illness, allowing for treatment before it became more severe. At this point, the number of pharmacists who can provide recommendations like Mr. Iijima are limited. In addition, with the stricter separation of pharmacies and clinics, there is a clear split between pharmacies that specialize mostly in filling prescriptions and drug stores that specialize in selling various goods. This has made so many patients reluctant to visit health-insurance approved pharmacies without a prescription, and patients are less likely to consult with the pharmacist at a drug store, since they are more focused on simply selling the product.

We believe there are two main challenges in recommending doctor visits when selling drugs requiring guidance or OTC drugs. First, is regarding the education that pharmacists receive. In order to consult with patients and provide recommendations, pharmacists would require a significant amount of knowledge on the medication. However, there is a possibility that the various pharmaceutical associations across Japan provide different levels of training, and even the possibility that some drug stores are not part of any pharmaceutical associations, making direct training from pharmaceutical associations difficult. In addition, if drug stores are to sell drugs requiring guidance, their pharmacists would need to receive training on those drugs in some way. Next, there is no database that manages all OTC drugs, meaning that even if the medication history of a patient was recorded, there is no easy way to share it with other healthcare professionals. Mr. Iijima also noted that doctors do not have a particularly high interest in utilizing OTC drugs for the treatment of patients.

Section 7　Proposals for the Promotion of Rx-to-OTC Switch

As explained, Japan has faced multiple reports of health issues caused by privately imported counterfeit drugs. In order to prevent the proliferation of these counterfeit drugs and to maintain a sustainable medical care provision system and universal health insurance system in a society with a declining birthrate and fast-growing aging population, it is becoming increasingly crucial to change the way citizens view healthcare, promote Rx-to-OTC switch, and to solve any challenges in those processes. In addition, with the promotion of self-medication being declared as a key policy for Japan, there is a need for the government to further push Rx-to-OTC switch. With these challenges in mind, we propose the following five policies to resolve the Rx-to-OTC switch lag in the country:

7-1. Establishment of a Rx-to-OTC Switch Roadmap Committee and the Prompt Development of KPIs and Roadmap for Rx-to-OTC Switch

The MHLW laid out the Roadmap for Further Promotion of Generic Medicine Use in April 2013, which has led to a quick uptake in generic drugs, even surpassing the government's initial estimates. In terms of OTC drugs, the Council for Regulatory Reform in its report outlined that it will "establish KPIs and roadmaps for Rx-to-OTC switch," showing the MHLW has a proactive stance towards Rx-to-OTC switch, but there are no specific efforts that have been made so far. There is a need to promptly develop KPIs and roadmaps for Rx-to-OTC switch by benchmarking other nations and looking at Rx-to-OTC switch from a broader perspective of promoting self-medication, helping to increase the life expectancy of Japanese citizens and improving quality of life.

7-2. Evaluation Council Restructuring (Implementation of a Target Timetable for Considerations, Clarification of Discussion Topics Required to Achieve KPIs, Creation of a Deadline from Submission of Written Proposal to Start of Deliberation)

As noted above, discussions in the Evaluation Council have often strayed from the fundamental goals of the discussions, which should be outlining the challenges in Rx-to-OTC switch and finding the solutions to those challenges. By laying out the discussion topics ahead of time, time for these discussions can be reduced. In addition, it is thought that after submission of a written request for ingredients considered in a Rx-to-OTC switch drug, there are cases where preparation for discussions with various societies has caused significant delays in the start of deliberation. This is thought to be a key reason for switch lag; therefore, we believe it is necessary to set a deadline such as one year between the submission of a written request to the start of deliberation.

7-3. Creation of an OTC Drug Database

OTC drugs contain the same active ingredients as prescriptions, which means attention is required for contraindications. However, there is no currently available database that connects OTC drug purchases to individuals, meaning healthcare professionals need to also be aware of possible OTC drug use by patients. Therefore, we believe there is a need to build a database like the pharmaceutical record book described below, to record OTC drug purchase history.

7-4. Creation of an OTC Pharmaceutical Record Book in Line with the Self-Medication Tax System

If OTC drugs become more widely available, efforts need to be made to encourage patients to use self-medication. The current self-medication tax system has been implemented as a way to do this, but as described above, it is an antiquated system requiring physical purchase receipts for declaration, obviously going against recent movements towards digitalization. A digital OTC pharmaceutical record book that can be accessed by smartphones, which also allows for the declaration for the self-medication tax system should be implemented as a way to encourage citizens to use the system.

7-5. Creation of a Japanese OTC Pharmaceutical Society

It is crucial to establish a system that creates a synergy between specialized treatment by doctors and self-treatment by patients, by amassing evidence regarding the use of OTC drugs in Japan and based on that evidence, creating a public forum to discuss the best way to utilize OTC drugs in the Japanese medical system. In addition, the Society could act as a way to research the challenges raised above and as a place to train those working with OTC drugs.

Section 8　Conclusion

There are many challenges regarding the promotion of Rx-to-OTC switch, and it is necessary to tackle the challenges one-by-one. The necessity for the promotion of Rx-to-OTC switch is clear, in aspects such as maintaining the sustainability of the medical care provision system and universal health insurance coverage system, increased demand for self-medication from Japanese citizens, and the prevention of health risks from counterfeit drugs. We hope that this policy proposal will act as a way to deepen understanding on the importance of promoting Rx-to-OTC switch and will accelerate the Rx-to-OTC switch of in-demand drugs.

Our Proposals

1. **Establishment of a Rx-to-OTC Switch Roadmap Committee and the prompt development of KPIs and roadmap for Rx-to-OTC switch**

2. **Evaluation Council Restructuring (implementation of a target timetable for considerations, clarification of discussion topics required to achieve KPIs, creation of a deadline from submission of written proposal to start of deliberation)**

3. **Creation of an OTC drug database**

4. **Creation of an OTC pharmaceutical record book in line with the self-medication tax system**

5. **Creation of a Japanese OTC Pharmaceutical Society**

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