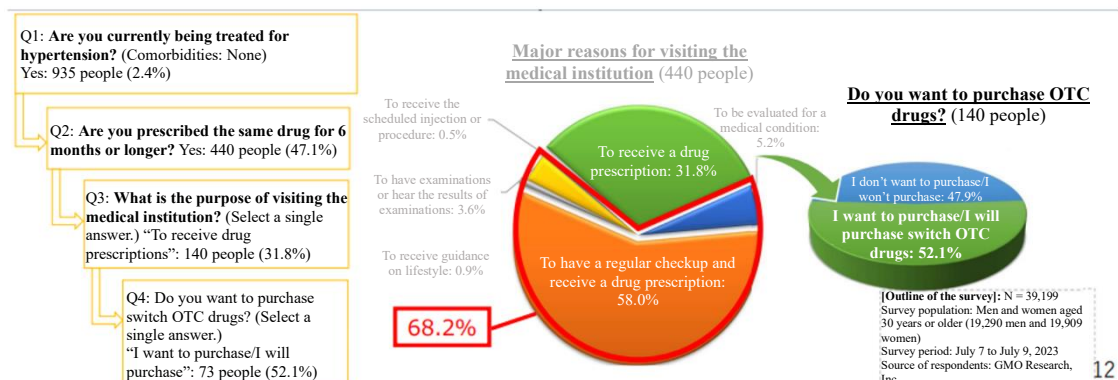


Addendum 1

Regarding drugs which are distributed in Japan through private importing and are not approved as over-the-counter (OTC) versions of prescription drugs (“switch OTC drugs”), Chapter 6 discusses the benefits of making those drugs available as switch OTC drugs (i.e., resolving “Rx-to-OTC switch lag”) with reference to some case studies in foreign countries. In this addendum, we provide supplementary information that cannot be covered in Chapter 6 and discuss the need for Rx-to-OTC switches by type of drug.

- Treatments for lifestyle diseases (mainly antihypertensives)
 - ✧ The material for the third advisory board meeting held by the Japan Self-Medication Industry provides the results of a Web survey of patients affected only by hypertension (n = 935) to identify the need for making antihypertensives available as switch OTC drugs. The survey found that 47.1% of patients received 6-month or longer prescriptions for the same drug (“long-term ditto prescriptions”). Of the patients with “long-term ditto prescriptions,” 31.8% responded that they had a doctor’s visit solely to receive prescription refills, suggesting that healthcare resources are not utilized properly. In addition, more than half (52.1%) of the patients having a doctor’s visit solely to receive prescription refills responded that they were willing to purchase OTC versions of antihypertensives if available, demonstrating that there is a significant need for Rx-to-OTC switches.¹
 - ✧ Based on these findings, the Japan Self-Medication Industry points out that it is necessary to make antihypertensives available as switch OTC drugs to establish a society which allows patients with stable symptoms to manage their illnesses through self-medication.

Figure 1: Survey of Patients Affected Only by Hypertension



(Source: Proposal materials for the 3rd meeting of the Advisory Board of the Japan Self-Medication Industry. Appendix [1\) New Consumer-oriented Strategies for Use of OTC Drugs](#). July 21, 2023)

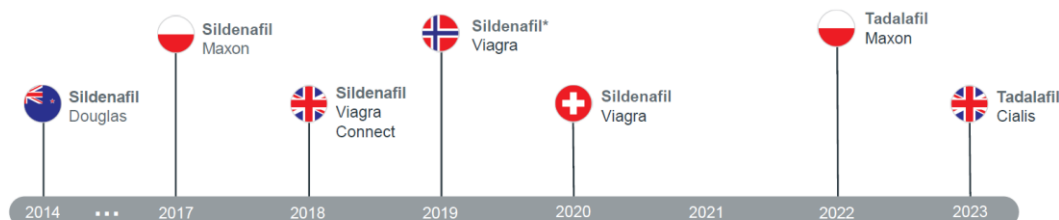
➤ ED treatments

- ✧ As mentioned in Chapter 6, ED treatments are among the likely targets for counterfeit medicines. In 2014, Viagra (nonproprietary name: sildenafil), one of the drugs indicated for the treatment of ED, became available to purchase from pharmacists without prescription in New Zealand for the first time in the world.² In contrast, Japan still restricts the availability of Viagra to prescription marketing status, resulting in a long “switch lag” of about 9 years.
- ✧ Tadalafil was first approved as a prescription drug for the treatment of ED in Australia on October 15, 2002 under the brand name of Cialis.³ In 2013, Cialis became the prescription ED drug with the largest market share in the world.⁴ Tadalafil was approved as an OTC drug in 2022 in Poland and in February 2023 in the UK.^{2,5} If an Rx-to-OTC switch of Cialis is approved in Japan as soon as possible, the switch lag can be minimized, which will help ensure that Japanese people have reliable and safe access to drugs.⁵

Figure 2: History of Rx-to-OTC Switches for ED Treatments in the World

Case study EU: Innovative Rx-to-OTC switches – Erectile dysfunction

Access restricted through interaction with a pharmacist (suitability check), dosage and pack size



*Norway changed its laws in 2018, to increase the number of OTC products on the market and created a third class called “non-prescription medicines with guidance”.

The absence of a pharmacy-only OTC status in the U.S. might have hindered more innovative switches, but new strategies are on the horizon

(Source: IQVIA, “[The Next Generation of Rx-to-OTC switch Focus on U.S, UK, and EU](#),” June 2023)

- *In vitro* diagnostics (IVDs) for sexually transmitted diseases
 - ✧ In Japan, Rx-to-OTC switches of IVDs for self-testing are approved for the following six tests: “urinary sugar,” “urinary protein,” “pregnancy test,” “ovulation prediction,” “COVID-19,” and “COVID-19/influenza.”⁶ On September 6, 2023, the Committee on Medical Devices and *In Vitro* Diagnostics held a meeting to discuss the proposed revision of the general principles on nonprescription IVDs, potentially leading to the approval of Rx-to-OTC switches of self-test IVDs for several tests.⁶ In the US, Rx-to-OTC switches of self-test IVDs are approved for 73 tests, including blood sample tests which are under consideration in Japan.⁷

Table 1: Self-Tests for which OTC IVDs are Available in US

Use of blood samples in OTC-IVDs outside Japan (US)



The US FDA discloses tests that can be conducted by consumers at home (OTC-IVDs), including many tests using blood samples.

Accessed in January 2020.

OTC-IVD名	検査項目	試料	検査方法	OTC-IVD名	検査項目	試料	検査方法
1. 妊娠検査薬	胎児糖蛋白	尿	速読式	2. 血糖値測定器	血糖値	末梢血	速読式
3. 梅毒検査薬	梅毒抗体	血清	速読式	4. 尿酸値測定器	尿酸値	血清	速読式
5. 感染症検査薬	感染症抗体	血清	速読式	6. 血圧測定器	血圧	末梢血	速読式
7. 血糖値測定器	血糖値	末梢血	速読式	8. 尿酸値測定器	尿酸値	血清	速読式
9. 尿酸値測定器	尿酸値	血清	速読式	10. 尿酸値測定器	尿酸値	血清	速読式
11. 尿酸値測定器	尿酸値	血清	速読式	12. 尿酸値測定器	尿酸値	血清	速読式
13. 尿酸値測定器	尿酸値	血清	速読式	14. 尿酸値測定器	尿酸値	血清	速読式
15. 尿酸値測定器	尿酸値	血清	速読式	16. 尿酸値測定器	尿酸値	血清	速読式
17. 尿酸値測定器	尿酸値	血清	速読式	18. 尿酸値測定器	尿酸値	血清	速読式
19. 尿酸値測定器	尿酸値	血清	速読式	20. 尿酸値測定器	尿酸値	血清	速読式
21. 尿酸値測定器	尿酸値	血清	速読式	22. 尿酸値測定器	尿酸値	血清	速読式
23. 尿酸値測定器	尿酸値	血清	速読式	24. 尿酸値測定器	尿酸値	血清	速読式
25. 尿酸値測定器	尿酸値	血清	速読式	26. 尿酸値測定器	尿酸値	血清	速読式
27. 尿酸値測定器	尿酸値	血清	速読式	28. 尿酸値測定器	尿酸値	血清	速読式
29. 尿酸値測定器	尿酸値	血清	速読式	30. 尿酸値測定器	尿酸値	血清	速読式
31. 尿酸値測定器	尿酸値	血清	速読式	32. 尿酸値測定器	尿酸値	血清	速読式
33. 尿酸値測定器	尿酸値	血清	速読式	34. 尿酸値測定器	尿酸値	血清	速読式
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39. 尿酸値測定器	尿酸値	血清	速読式	40. 尿酸値測定器	尿酸値	血清	速読式
41. 尿酸値測定器	尿酸値	血清	速読式	42. 尿酸値測定器	尿酸値	血清	速読式
43. 尿酸値測定器	尿酸値	血清	速読式	44. 尿酸値測定器	尿酸値	血清	速読式
45. 尿酸値測定器	尿酸値	血清	速読式	46. 尿酸値測定器	尿酸値	血清	速読式
47. 尿酸値測定器	尿酸値	血清	速読式	48. 尿酸値測定器	尿酸値	血清	速読式
49. 尿酸値測定器	尿酸値	血清	速読式	50. 尿酸値測定器	尿酸値	血清	速読式

11

(Source: Material 2 from the Japan Association of Clinical Reagents Industries and Japan Self-Medication Industry for the 6th meeting of the Cabinet Office Working Group on Medical Care and Nursing Care. [“Promotion of Switches from Prescription In Vitro Diagnostics \(IVDs\) to nonprescription IVDs \(Rx-to-OTC Switches\),”](#) February 13, 2020)

Addendum 2

On Monday, October 2, 2023, the Japan Public Affairs Association held a forum intended for the press, titled “Urgent Proposals for the Promotion of Rx-to-OTC Switches,” to release the policy proposal document “Private Importing Issues Causing the Distribution of Counterfeit Medicines and Five Proposals for the Promotion of Rx-to-OTC Switches.”

This forum began with Keynote Lecture 1, in which Mr. Masaki Muto, Social Welfare Corporation Japan Medical Mission Kinugasa Hospital Group Adviser and a member of the Japan Association of Healthcare Initiative, who serves as an adviser for the Japan Public Affairs Association and supervised the preparation of the policy proposal document, delivered a lecture titled “Private Importing Issues Causing the Distribution of Counterfeit Medicines and Five Proposals for the Promotion of Rx-to-OTC Switches” to share the objectives of releasing the policy proposal document and its

outline. This was followed by Keynote Lecture 2, in which Mr. Masahiro Nishijima, former president of Showa Pharmaceutical University and Head of the Counterfeit and Illegal Drugs Information Center, spoke about “Health Problems, etc. Related to Privately Imported Drugs.”

Mr. Muto commented, “Taking into consideration the ongoing efforts to change the way physicians work, it is important to identify the value of OTC drugs in the current healthcare environment where physicians and pharmacists increasingly collaborate to provide patient care.” As case studies, he also mentioned the potential benefits of making “treatments for lifestyle diseases,” “ED treatments,” and “IVDs for sexually transmitted diseases” available as OTC drugs. He ended his lecture by emphasizing the need to increase the availability of switch OTC drugs for the promotion of self-medication and proposing the actions required to achieve this goal.

After the keynote lectures, a panel discussion was held in which Mr. Soichiro Isobe, President of the Japan Self-Medication Industry, Mr. Hiroya Iijima, Permanent Director of the Ueda Pharmacists Association, and Mr. Masataka Sata, Professor, Department of Cardiovascular Medicine, Tokushima University Graduate School of Biomedical Sciences and President of the Japan Society for Vascular Failure, discussed three topics (Topic 1 “Challenges and social benefits associated with Rx-to-OTC switches,” Topic 2 “Benefits that the promotion of Rx-to-OTC switches provides to consumers,” and Topic 3 “Actions that the government should take for the promotion of Rx-to-OTC switches”). Mr. Isobe expressed an opinion that, “It is important that switch OTC drugs with reliable quality should be available as treatment options. This should also be considered in terms of protection against the risk of counterfeit medicines.” Mr. Iijima commented, “If more Rx-to-OTC switches are approved, pharmacists will play a more important role, and pharmacies will be the first point of access to healthcare for residents in the community, resulting in a reduced burden on physicians and helping ensure the sustainability of the universal health insurance system.” In addition, Mr. Sata supported the efforts to increase the availability and utilization of switch OTC drugs, saying, “It is important to establish a healthcare environment where pharmacists provide medication counseling by leveraging OTC drugs and instruct patients to see a doctor as needed.”

Below are major comments given by panelists.

<Mr. Muto>

- In terms of prescription refills, pharmacists at pharmacies and physicians can increasingly collaborate in patient care. If such collaboration becomes well-established, it will be possible to implement Rx-to-OTC switches starting with drugs for which prescriptions can be refilled.

<Mr. Nishijima>

- The future challenge is to ensure that health support pharmacies will properly handle OTC drugs as well and promote appropriate self-medication as part of community healthcare and home care.
- The biggest problem associated with counterfeit medicines is that patients confuse private importers' websites with ordinary online sales websites. This makes it necessary to improve the drug literacy of the entire Japanese population.
- I believe that the most important of the proposals is the establishment of a society for self-medication. This is because the framework for medically clarifying and discussing the risks and benefits of OTC drugs should be provided by an academic society. In addition, if the society is established, universities may provide relevant courses, which will help improve education on OTC drugs.

<Mr. Isobe>

- The true separation of dispensing and prescribing functions using OTC drugs is required in the face of the 2040 problem which will cause shrinking workforce in the entire society, including the health provider community, and resultant scarceness of medical resources.
- The personal importation increases risk for influx of counterfeit medicines, which would be repelled if there was a robust domestic distribution system of genuine drugs.

<Mr. Sata>

- Incremental task-shifting is underway to avoid possible physicians' refusal to see patients as a consequence of workstyle reform. This includes efforts by pharmacists

to provide appropriate medication counseling and collect adverse drug reactions, and it would be more desirable if self-medication was spread among patients.

- With regard to ED treatments, it is presumed that in the current situation, many of individuals with symptoms suggestive of ED cannot visit medical institutions partly because they feel embarrassed. I suspect that untreated ED and associated unsuccessful sexual intercourse may leave lots of couples unable to have children. The availability of the OTC versions of ED treatments is desired, which may improve ED symptoms, increase their chances of fathering children, and as a result, overcome the declining birthrate.

<Mr. Iijima>

- The objective of pharmacists' work is to contribute to health promotion and better quality of life (QOL) of patients in the local community, and it is important to gain trust from other professions by reexamining the current way of being of a pharmacy as an organization exclusively focusing on profit-making.
- If efforts by pharmacists to provide medication counseling and encourage patients to visit a medical institution accumulate with increasing public access to drugs by promoting Rx-to-OTC switches, pharmacies may become the first point of access to healthcare for residents in the community and contribute to ensuring the sustainability of the universal health insurance coverage.
- The availability of OTC versions of test drugs for sexually transmitted disease may facilitate proper sharing of information and encouraging patients to visit a medical institution by pharmacists, helping prevent the spread of the infection.

■ References

- [1] Proposal materials for the 3rd meeting of the Advisory Board of the Japan Self-Medication Industry. Appendix [1\) New Consumer-oriented Strategies for Use of OTC Drugs](#). July 21, 2023
- [2] IQVIA. [The Next Generation of Rx-to-OTC switch Focus on U.S, UK, and EU](#). June 2023
- [3] Yamaguchi T, et al. [Pharmacological, Pharmacokinetic, and Clinical Profile of Tadalafil \(Cialis®\)](#). Folia Pharmacol Jpn 2008

[4] Press release from Eli Lilly Japan K.K. and Nippon Shinyaku Co., Ltd. [Cialis® Becomes #1 Share in the Worldwide Erectile Dysfunction \(ED\) Drug Market](#). August 29, 2013

[5] Press release from GOV.UK. [MHRA reclassifies Cialis Together tablets to a Pharmacy medicine](#). March 14, 2023

[6] Material 1-1 from the Japan Association of Clinical Reagents Industries and Japan Self-Medication Industry for the 2nd 2023 meeting of the Committee on Medical Devices and In-vitro Diagnostics. [Review of General Principles for "OTC Test Drugs": To Become an Important Bridge between the Public and Medical Care](#). September 6, 2023

[7] Material 2 from the Japan Association of Clinical Reagents Industries and Japan Self-Medication Industry for the 6th meeting of the Cabinet Office Working Group on Medical Care and Nursing Care. [Promotion of Switches from Prescription *In Vitro* Diagnostics \(IVDs\) to nonprescription IVDs \(Rx-to-OTC Switches\)](#), February 13, 2020