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Changes in Regional Medical Collaboration System and Functions in Community Pharmacy Before and After the Enforcement of the Amended Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices in Tokyo

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Over the past few decades, the number of older adults in desperate demand of social support is inevitably increasing with an aging population. Thus, there is a need for a social framework that can improve the quality of life of older adults. In Japan, where the population faces a super-aging society, the aim is to establish a community-based integrated care system that supports the elderly throughout the community. In August 2021, the Japanese government partially amended the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices to expand the flexible healthcare provision, which forms the basis of that system. This amendment encourages patients to choose pharmacies that better meet their needs by establishing a framework for publicly certifying pharmacies that play essential roles in community healthcare, including home healthcare, and pharmacies that can provide specialized medical care. However, the actual effects of the intervention remain unclear. Thus, we explored changes in efforts related to regional medical collaboration and functions in community pharmacies before and after the enforcement of the amended Act. Our survey revealed that the amendment increased the stockpiles of generic medicines at each pharmacy without a clear increase in the number of employees. Additionally, there was an across-the-board improvement in the provision of information to other medical providers and patients. These results indicated that the amendment to the Act directly or indirectly promoted a shift from conventional pharmacy to a more patient-oriented approach.

Key words community pharmacy, regional medical collaboration system, pharmacy functional information provision system, pharmacy vision for patients, enforcement of amended the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices

INTRODUCTION

In recent years, the Japanese population has aged rapidly. It is anticipated that the proportion of people aged 65 years or older will reach 30.3%, and the percentage of people aged 75 years or older will increase to 18.1% of the total population by 2025.[1)] Furthermore, as an aging society, the proportion of older adults who necessarily require support is also increasing.[2)] Under such circumstances, the Ministry of Health, Labor, and Welfare (MHLW) proposed the establishment of the "community-based integrated care system" aimed at ensuring housing, medical care, long-term care, prevention, and lifestyle support in a comprehensive manner by 2025.[3)] The establishment of the system is essential for making the medical insurance system sustainable and also has certain advantages for patients, including: (1) improved safety and efficiency through centralized management of medication information; (2) a 24-h response system for emergencies; and (3) home medication counseling for the very elderly and people with disabilities, among others. Therefore, community pharmacies have essential roles in collaborating with other regional medical providers.[3)]

Prescription receipt rates at community pharmacies in 2022 are expected to exceed 75%,[4)] and the separation between pre-

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scriptions and dispensing is expected to continue. Under such circumstances, in the medical insurance system, the technical fee out of the cost of total medical care, including dispensing, was approximately 2 trillion yen in the fiscal year 2021,[5] an increase of 7% compared with the previous fiscal year. However, since community pharmacies mainly dispense medicines, they do not fulfill their intended functions such as medical collaboration with medical providers, and there are opinions that the significance and advantages of the separation of prescription and dispensing are not experienced by patients and other medical providers.[6] To realize a patient-oriented system of separation of dispensation and prescription of medicines, MHLW established a goal for family pharmacists and pharmacies called the "pharmacy vision for patients" on October 23, 2015.

The Japanese government has already launched an initiative to collect and publicize information on the state of collaboration between community pharmacies and other medical providers, called the pharmacy functional information provision system, to encourage patient-centered pharmacy choices.[7] This system was initiated on April 1, 2007, as part of the efforts to share information so that patients can make appropriate choices regarding community pharmacies; in this system, the prefectural government publishes the necessary information so that patients and local residents can make appropriate choices about community pharmacies. In Tokyo, community pharmacy information is reported to Tokyo Metropolitan Government using both the community pharmacy functional information report and the Tokyo Metropolitan Government's independently published item report.[8] These reports include a section on regional medical collaboration, and community pharmacies must report on the establishment status of the regional medical collaboration system.[8] In a super-aging society, establishing a system of collaboration between regional medical providers and family pharmacies is extremely important. Therefore, it is necessary to enhance the functions of community pharmacies to ensure that patients can select appropriate community pharmacies not only from the viewpoint of operating hours and location but also pharmacy function. Additionally, for all community pharmacies, to enhance their functions, understanding the characteristics of community pharmacies that have established regional medical collaboration systems is essential. In 2020, we reported the establishment of a regional medical collaboration system using the community pharmacy functional information report in Tokyo.[9] According to this report, the characteristics of community pharmacies that have established a regional medical collaboration system include a large number of pharmacists, medicine stockpiles, and efforts to improve the caliber and aspirations of pharmacists.[9]

The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter referred to as the Act) aims to improve health and hygiene of the people by providing the control required for securing the quality, efficacy and safety of pharmaceuticals, etc. in Japan. The amendment resulted in the enforcement of the accreditation system for "regional collaborative pharmacy" and "specialized medical institution cooperating pharmacy"[10] in efforts to enhance regional medical collaboration. This system is a public certification system for community pharmacies to enable patients to use medicines with a sense of security in the region where they are accustomed to living by reviewing the state of community pharmacies and pharmacists and enabling them to select community pharmacies that suit their own needs.

As the first step in evidence-based policy making, it is important to create and accumulate evidence that will enable us to understand the actual situation. The new implementation of the public certification system would prompt patients to select community pharmacies for appropriate use from the point of view of the community pharmacy function rather than the location of the community pharmacy, and further advances the patient-centered separation between prescription and dispensing; however, there is no report that quantitatively evaluates how the enforcement of the amended Act has changed the status of the establishment of a regional medical collaboration system. Therefore, this study was conducted to quantitatively evaluate the state of progress in the regional medical collaboration system, including medicine-stockpiles, the number of employees, and execution of information provision, caused by the enforcement of the amended the Act.

MATERIALS AND METHODS

Obtaining Original Data on Eligible Community Pharmacies The Japanese government requires that all pharmacies report their functional information (community pharmacy functional information report). In addition to the functional report, Tokyo Metropolitan Government also collected unique information on pharmacy functions (Tokyo Metropolitan Government's independently published item report). The present analysis was a complete enumeration of insurance pharmacies in Tokyo from these two reports, before and after the amendment of the Act.

As of November 1, 2020 (before the enforcement of the amended the Act), 6,691 pharmacies had responded to the reports; 160 pharmacies without insurance designation and 30 pharmacies that did not accept any prescriptions were excluded (total n = 6,483). As of July 27, 2022 (after enforcement), 6,913 pharmacies had responded to the reports; 191 pharmacies without insurance designation and 26 pharmacies that did not accept any prescriptions were excluded (total n = 6,696). All pharmacy information was statistically summarized to ensure that individual pharmacies were not identified.

Evaluation of Efforts for the Regional Medical Collaboration and Analytical Method To evaluate the effort to establish a community-based integrated care system, items listed in "regional medical collaboration system" in the "provision of services and regional medical collaboration system" were used (Table 1). Items listed under "D) others" and "5) participation in awareness-raising activities for local residents" were not used for the evaluation because they are not direct indicators for the establishment of a collaborative system among medical providers.

In addition to the "regional medical collaboration system", the status of efforts to improving the quality of community pharmacies (the following items) was evaluated: "implementation of the case review meeting," "implementation of the patient satisfaction survey," and "enrollment of education system-qualified pharmacists". These items were extracted from the community pharmacy functional information report. The evaluation items in this study are shown in Table 2.

In order to confirm changes in the community pharmacy size before and after the enforcement of the amended Act, the

Table 1. Regional Medical Collaboration System in the Community Pharmacy Functional Information Report

1) Availability of medical collaboration
A) Collection of cases in which medicine-related adverse events were prevented or avoided
B) Implementation of the pharmacist's duties according to protocols agreed upon with the physician
C) Standardization of medicines used through collaboration among regional hospitals (including clinics)
D) Others
2) Participation in a regional medical information collaboration network
3) Sharing information at the of discharge
4) Providing information pertaining to recommendations with medical providers for medical consultation
5) Participation in awareness-raising activities for local residents

Table 2. Evaluation Items

Status of efforts for regional medical collaboration
1) Availability of medical collaboration
A) Collection of cases in which medicine-related adverse events were prevented or avoided
B) Implementation of the pharmacist's duties according to protocols agreed upon with the physician
C) Standardization of medicines used through collaboration among regional hospitals (including clinics)
2) Participation in a regional medical information collaboration network
3) Sharing information at the of discharge
4) Providing information pertaining to recommendations with medical providers for medical consultation
Status of efforts related to improving the quality of community pharmacies
5) Implementation of case review meeting
6) Implementation of patient satisfaction survey
7) Enrollment of education system-qualified pharmacists

following supplementary items were also evaluated: number of prescriptions demanded, number of pharmacists, number of stockpiled prescription-only medicines, number of stockpiled generic medicines, and number of stockpiled over-the-counter (OTC) medicines. The number of prescriptions demanded and the number of pharmacists were extracted from the community pharmacy functional information report, and the number of stockpiled prescription-only medicines, generic medicines and OTC medicines were extracted from the Tokyo Metropolitan Government's independent publicized item report. Of these, "prescription demand" is the actual number of patients who brought prescriptions between January 1 and December 31 of the previous year. In terms of the number of stockpiled prescription-only medicines, including generic medicines, the MHLW announced that the number of prescription-only medicines as of November 1, 2020, was 14,548, including 7,015 generic medicines,[11] and as of July 27, 2022, was 13,653, including 5,900 generic medicines.[12] Therefore, community pharmacies that answered with values greater than these were excluded from the evaluation.

All statistical analyses were performed using Microsoft Excel 365 (Microsoft Corp., Washington, USA). Unless otherwise noted, the median and interquartile range (IQR) are given as statistically representative values.

RESULTS

Community Pharmacy Size Figure 1 illustrates the number of patients who brought prescriptions, the number of pharmacist employees, and stockpiled amounts of prescription-only medicines, generic medicines, and OTC medicines from Tokyo Metropolitan Government's independently published item report at the time of reporting.[7,13] After the amendment of the Act, the number of patients who brought prescriptions declined (median [IQR]: 13,050 [8,016–20,724] to 11,340 [6,910–18,509], patients/year) and the number of pharmacists per pharmacy did not change appreciably. While there was no apparent change in the amount of stockpiled prescription-only medicines and OTC medicines, the stockpiled generic medicines tended to increase (400 [291–540] to 479 [340–600], products/pharmacy).

Status of Efforts for Regional Medical Collaboration Table 3 shows the percentage of community pharmacies that responded "yes" to the items listed in "regional medical collaboration system" in the community pharmacy functional report.

In 2020, the effort with the highest implementation rate was "medical collaboration". This was followed by "providing information pertaining to recommendations for medical providers regarding medical consultation", "participation in a regional medical information collaboration network", and the effort with the lowest implementation rate was "sharing information at discharge". Additionally, among medical collaboration, the effort with the highest rate of implementation was the "collection of cases in which medicine-related adverse events were prevented or avoided", and the effort with the lowest implementation rate was the "standardization of medicines used through collaboration among regional hospitals". These results showed similar behavior in 2022 after the enforcement of the amended Act, and the implementation rate of all efforts related to regional medical collaboration after the enforcement of the amended Act was higher than before the enforcement of the amended Act.

Figure 2 illustrates the number of community pharmacies that implemented all four efforts and the number of community pharmacies that did not implement all four efforts. In 2020, the number of community pharmacies that implemented all four efforts was 629 (9.7%), while there were 2,534 (39.1%) community pharmacies that did not implement them. Conversely, in 2022, the number of community pharmacies that implemented all four efforts was 1,078 (16.1%), while there were 2,137 (31.9%) community pharmacies that did not imple-

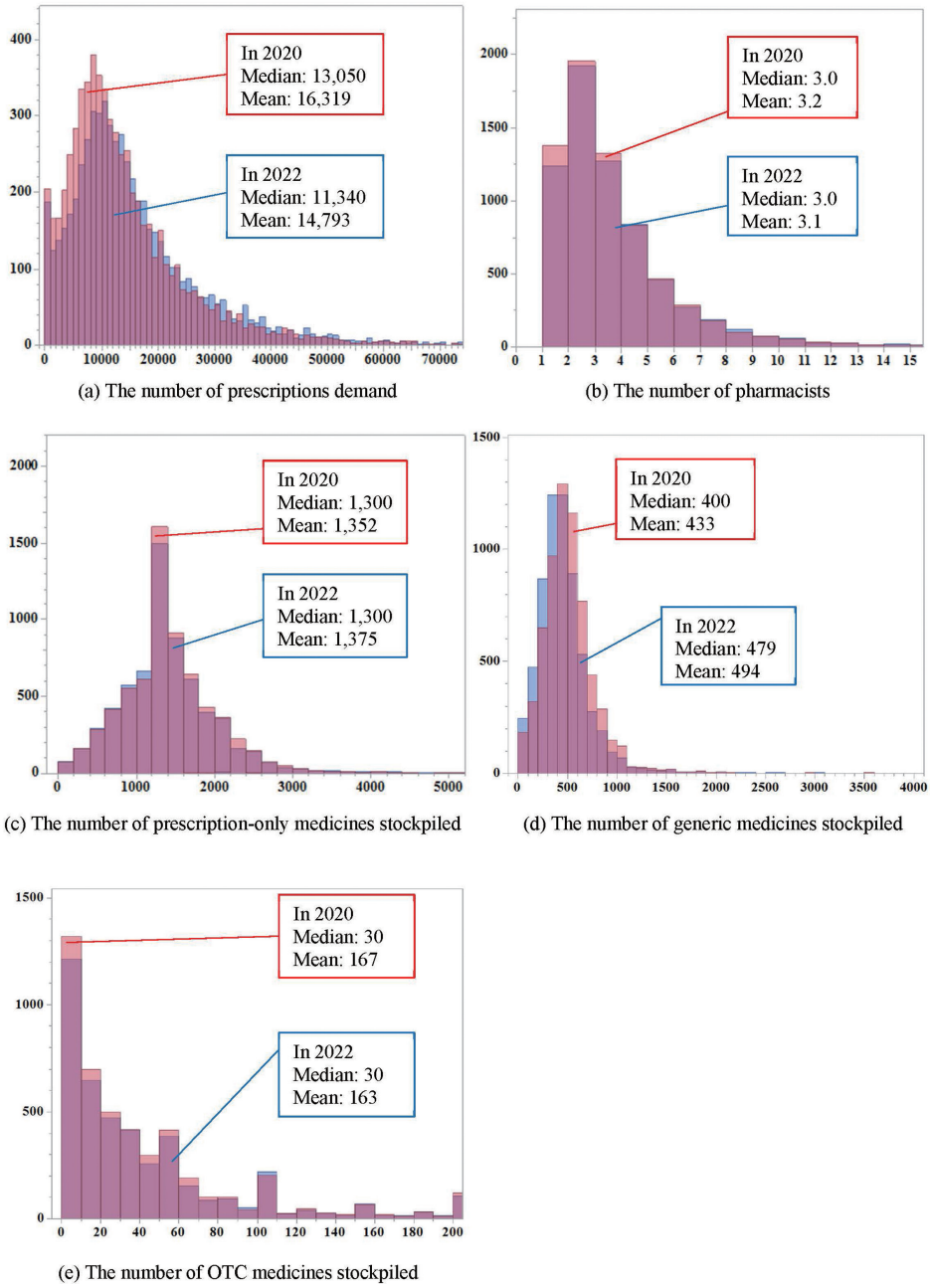

Fig. 1. Change in Size of Community Pharmacies

The red parts represent 2020, the blue parts represent 2022, and the purple parts overlaps 2020 and 2022 parts. The vertical axis represents the number of community pharmacies and the horizontal axis represents the title of each figure. These values were summarized using data collected by Tokyo Metropolitan Government, based on a pharmacy functional information provision system. According to the MHLW, the number of prescription-only medicines was 14,548 as of November 1, 2020, and 13,653 as of July 27, 2022. The numbers of generic medicines were 7,015 and 5,900, respectively. Therefore, community pharmacies that responded with values greater than these were excluded.

Table 3. Status of Efforts for Regional Medical Collaboration

	2020	2022
	The number of community pharmacies (%)	**The number of community pharmacies (%)**
Medical collaboration	3,630 (56.0%)	4,152 (62.0%)
Collection of cases in which medicine-related adverse events were prevented or avoided	3,612 (55.7%)	4,124 (61.6%)
Implementation of the pharmacist's duties according to protocols agreed upon with the physician	380 (5.9%)	528 (7.9%)
Standardization of medicines utilized through a collaboration among regional hospitals (including clinics)	227 (3.5%)	355 (5.3%)
Participation in a regional medical information collaboration network	1,408 (21.7%)	1,973 (29.5%)
Sharing information at discharge	1,063 (16.4%)	1,675 (25.0%)
Providing information pertaining to recommendations with medical providers for medical consultation	1,757 (27.1%)	2,609 (39.0%)

These values summarize the data collected by Tokyo Metropolitan Government based on the pharmacy functional information provision system.

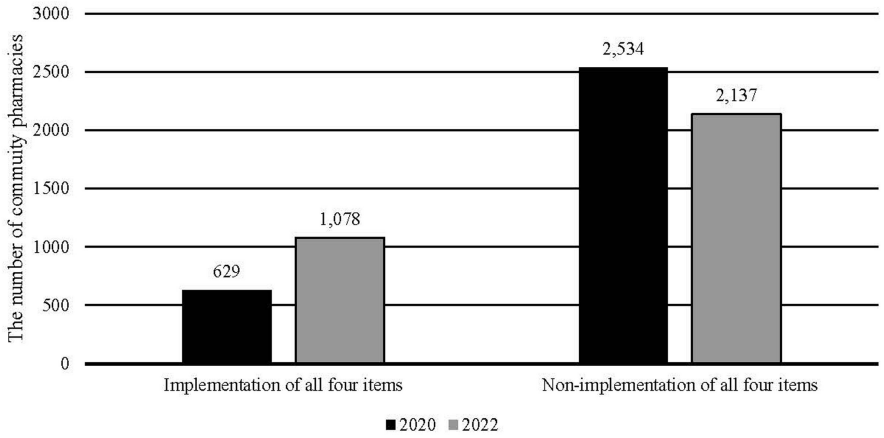

Fig. 2. Number of Community Pharmacies that Have Implemented Regional Medical Collaboration Efforts

The following four efforts listed in the community pharmacy functional information report were evaluated; availability of medical collaboration, participation in a regional medical collaboration network, sharing information at the of discharge and providing information pertaining to recommendations with medical providers for medical consultation.

Table 4. Status of Efforts Related to Improving the Quality of Community Pharmacies

	2020	2022
	The number of community pharmacies (%)	**The number of community pharmacies (%)**
Implementation of case review meeting	3,500 (54.0%)	3,752 (56.0%)
Implementation of patient satisfaction survey	868 (13.4%)	892 (13.3%)
Enrollment of education system-qualified pharmacists	4,635 (71.5%)	5,030 (75.1%)

These values summarize the data collected by Tokyo Metropolitan Government based on the pharmacy functional information provision system.

ment them.

Status of Efforts Related to Improving the Quality of Community Pharmacies Table 4 illustrates the status of items related to improving the quality of community pharmacies in the community pharmacy functional reports.

Overall, 3,500 (54.0%) and 3,752 pharmacies (56.0%) enforced "implementation of case review meeting" in 2020 and 2022; 868 (13.4%) and 892 pharmacies (13.3%) implemented "implementation of patient satisfaction survey" in 2020 and 2022. Further, 4,635 (71.5%) and 5,030 pharmacies (75.1%) implemented "enrollment of education system-qualified pharmacists" in 2020 and 2022.

DISCUSSION

This study analyzed community pharmacies in Tokyo using individual data from the functional reports of community pharmacies and Tokyo Metropolitan Government's independently published item reports collected under the pharmacy functional information provision system. These reports were prepared to collect basic information on community pharmacies, such as their size and hours of operation. From these reports, we believe it is vital to confirm the implementation status of the measures leading to the establishment of the regional medical collaboration system and whether there were any changes before and after the enforcement of the amended Act. On the other hand, the results obtained in this study do not necessarily correspond to the results obtained in all prefectures because the pharmacy functional information located in Tokyo was used and the differences in regional characteristics are not taken into account. The number of community pharmacies located in all prefectures is 60,951 (as of the end of FY2020)[14] and 62,375 (as of the end of FY2022)[15], with over 10% of community pharmacies located in Tokyo. Therefore, it was considered meaningful to use only information on the functions of community pharmacies located in Tokyo.

As a result, the demand for prescriptions decreased by 2022 compared with 2020. In 2020, a large number of patients contracted coronavirus disease in Japan during the global pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-COV-2). Hence, it was suggested that the number of patients who brought prescriptions in 2020 would have been larger than that in 2022 when the SARS-COV-2 pandemic was relatively stable. However, there was no significant change in the number of community pharmacists, stockpiled prescription-only medicines and OTC medicines stockpiled during both times. Nonetheless, the average and median values of the number of stockpiled generic medicines increased in 2022 compared to 2020. Stockpiled prescription-only medicines included generic medicines.[9] In Japan, increasing the number of stockpiled generic medicines among the total number of stockpiled medicines has become more profitable for community pharmacies.[16] These changes may be due to recent revisions in the number of rewards for dispensing medicines.[16] Hence, it is suggested that the ratio of stockpiled generic medicines out of stockpiled prescription-only medicines may be increasing, and the ratio of stockpiled other medicines (such as original medicines, etc.) may be decreasing.

As shown in Table 3, the implementation rate of all evaluated items (availability of medical collaboration, participation in a regional medical information collaboration network, sharing information at the of discharge and providing information pertaining to recommendations with medical providers for medical consultation) after the enforcement of the amended Act was higher than before the enforcement. Similarly, the number of community pharmacies which engaged in the eval-

uated items completely has increased after the enforcement of the amended Act (Fig. 2). The reason for the increase in the number of community pharmacies with the high engagement for regional medical collaboration would be partially associated with the enforcement of the amended Act. Of the items related to improving the quality of community pharmacies, there was an upward trend of the enrollment rate educational system-qualified pharmacists, who are required to be family pharmacists, although there was negligible change in the implementation rate of the patient satisfaction survey. This upward trend is expected to further increase the number of family pharmacists and pharmacies that play an essential role in community healthcare, and may realize to promote individualized healthcare, the purpose of the family pharmacists and pharmacies. In our data aggregation, the implementation rate of case review meetings to improve the status of medical compliance, the content of guidance, and strategies for polypharmacy also increased in 2022 compared to 2020, albeit only slightly (Table 4). Coupled with the abovementioned increase in the enrollment rate of educational system-qualified pharmacists, both occasions to consider individualized healthcare and contact points for regional patients would be increased. These increases should provide a good opportunity for discussion on how to promote shifting from the objective duties such as prescribing and managing medicines to interpersonal duties, in the "Vision for Pharmacies for Patients" advocated by MHLW.

However, it was difficult to ascertain the details of the changes in the measures leading to the establishment of the regional medical collaboration system since the tabulation of "yes" or "no" indicates whether this system enabled the implementation of the measures leading to the establishment of the system that was in place in each item. Based on the above, the limitations of this survey using administrative data include the following. First, the data used for analysis was reported at different time points. The Tokyo metropolitan government collects response information using the data of "t-Yakkyoku Info", which is managed by Tokyo metropolitan government, and each community pharmacy can update pharmacy information at any time. Comparison between pharmacies at a singular time point is necessary to examine changes that occur over a period of time in a precise regional medical collaboration system. This survey used the response information registered as of November 1, 2020, and July 27, 2022, and it was unclear when each community pharmacy reported the information. The second is the number of prescription-only and generic medicines stockpiled. These items indicate the number of items rather than the number of medicines used. However, when we evaluated the responses of each pharmacy, several answered unexpectedly. Third, community pharmacists' awareness was unclear. Although this survey revealed a change in the implementation status of the regional medical collaboration in each community pharmacy, it did not reveal individual pharmacists' willingness to establish such a system. Therefore, to understand the implementation status of measures leading to the establishment of a more detailed regional medical collaboration system, it was considered necessary to survey the awareness of community pharmacists regarding the provision of information to medical providers and their attitudes toward the establishment of a regional medical collaboration system. Moreover, it is impossible to build a regional medical collaboration system simply by raising awareness among community pharmacists. Therefore, it is necessary to investigate awareness of providing information to community pharmacies and other medical providers, including pharmacists engaged in regional hospitals, as well as building a regional medical collaboration system in the future. Despite the above limitations, there has been a trend of shifting to interpersonal duties even the SARS-COV-2 pandemic which interpersonal duties should be avoided. This suggests that the shift to interpersonal duties will be highlighted as the SARS-COV-2 pandemic stabilizes.

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Data Source and Availability The Pharmaceutical Affairs Section, Health and Safety Division, Bureau of Public Health, Tokyo Metropolitan Government, provided information on the responses to these reports.

Conflict of interest The authors declare no conflict of interest.

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