Pharmaceuticals and Medical Devices Safety Information

May 2026
No.429

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This *Pharmaceuticals and Medical Devices Safety Information (PMDSI)* publication is issued when safety information collected by the Ministry of Health, Labour and Welfare (MHLW) is made available. It is intended to facilitate safer use of pharmaceuticals and medical devices by healthcare providers. The PMDSI is available on the Pharmaceuticals and Medical Devices Agency (PMDA) website (https://www.pmda.go.jp) and on the MHLW website (https://www.mhlw.go.jp/).

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PMDA メディナビ 安全性情報をメールで配信

Register here

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Pharmaceuticals and Medical Devices Safety Information No.429

Ministry of Health, Labour and Welfare

[Outline of Information]

No.	Subject	Measures	Outline of Information	Page
1	The Manuals for Management of Individual Serious Adverse Drug Reactions		The MHLW prepared the Manuals for Management of Individual Serious Adverse Drug Reactions from fiscal year (FY) 2005 to 2010 and started to revise the Manuals in FY 2016 based on the latest knowledge. In this issue, the progress of the revisions of the Manuals, further plans, and measures to increase awareness will be introduced.	4
2	The survey results on the status of acquisition, communication, and use of drug safety information at hospitals and pharmacies and desirable directions		Since FY 2010, the PMDA has been conducting surveys to understand the status of acquisition, communication, and use of safety information at medical institutions, etc. and to consider measures to promote the use of safety information for the purpose of ensuring steady implementation of the safety measures taken and further patient safety. In the survey in FY 2025, PMDA also conducted a survey targeting physicians to understand the status of use of drug safety information in medical practice while continuing the existing survey mainly targeting pharmacists as well as a follow-up survey on the status of acquisition of information in association with digitalization of package inserts and the status of utilization of RMP. This issue introduces results of surveys on the following matters and discussion of the results (desirable directions): 1) acquisition of information, 2) the status of understanding and use of risk communication tools such as the RMP, which was identified as an issue in the previous surveys, and 3) the status of use of GS1 barcodes.	9
3	Regorafenib hydrate	*P* *C*	Regarding the revision of PRECAUTIONS of package inserts of drugs in accordance with the Notification dated April 21,2026, this section will present the details of important revisions as well as the case summary serving as the basis for these revisions.	20
4	(1) Infliximab (genetical recombination), (2) Infliximab (genetical recombination) [Infliximab Biosimilar 1], (3) Infliximab (genetical recombination) [Infliximab Biosimilar 2], (4) Infliximab (genetical recombination) [Infliximab Biosimilar 3], (5) Etanercept (genetical recombination) (6) Etanercept (genetical recombination) [Etanercept Biosimilar 1], (7) Etanercept (genetical recombination) [Etanercept Biosimilar 2] and 4 others	*P*	Revisions of PRECAUTIONS (No. 369)	22
5	List of Products Subject to Early Post-marketing Phase Vigilance		List of products subject to Early Post-marketing Phase Vigilance as of March 31, 2026	26

E : Distribution of Dear Healthcare Professional Letters of Emergency Communications
R : Distribution of Dear Healthcare Professional Letters of Rapid Communications
P : Revision of PRECAUTIONS
C : Case Reports

Reporting of safety information such as adverse reactions to the MHLW is a duty of healthcare professionals.

When healthcare professionals, including physicians, dentists, and pharmacists, notice any adverse reactions, infections, or malfunctions associated with drugs, medical devices, or regenerative medical products, please report safety information to the MHLW directly or through the marketing authorization holders. Pharmacists and registered salespersons in a drugstore or pharmacy are also required to report any adverse drug reactions.

Please submit your report through the  Report Reception Site.

(This service is available only in Japanese.)
https://www.pmda.go.jp/safety/reports/hcp/0002.html

1

The Manuals for Management of Individual Serious Adverse Drug Reactions

1. Introduction

Conventional safety measures implemented in Japan had been drug-oriented and mainly “alert-issue” and “post-event response” types, i.e., information of adverse drug reactions (ADRs) was collected and evaluated for each drug and notified to the clinical settings. However,

(1) ADRs can occur in organs in which clinicians are not specialized

(2) The incidence of serious ADRs is generally low, and some clinicians may have little experience with such events.

Therefore, there was concern that detection of a disease as an adverse reaction may be delayed, leading to progression to a serious condition depending on the situation.

Therefore, the Ministry of Health, Labour and Welfare (MHLW) has implemented the "Project of Comprehensive Measures for Serious ADRs" (hereinafter referred to as the "Project," the Project has been ongoing as the “Development Project of the Manuals for Management of Individual Serious ADRs” since FY 2021.) since 2005 in order to develop safety measures that "predict" and "prevent" ADRs, focusing on diseases caused by the use of drugs, in addition to conventional drug-oriented ADR safety measures, and to promote research to elucidate the mechanism of ADRs, etc. In this project, "The Manuals for Management of Individual Serious ADRs" (hereinafter referred to as the "Manuals") were compiled from FY 2005 to FY 2010 by the Committee on the Comprehensive Actions for Serious ADRs who reviewed and compiled the drafts prepared by manual preparation committees organized in related academic societies through discussion with the Japanese Society of Hospital Pharmacists (JSHP) as entrusted by the MHLW in this project. The drafts were prepared with reference to academic papers, various guidelines, health and labor science research project reports, PMDA health and welfare service reports, etc.

In order to promote further utilization of the Manuals after a certain period of time has elapsed since its compilation, revisions based on the latest knowledge have been made over the five years since FY 2016, with the cooperation of related academic societies and others. In addition, we continue to revise the Manuals and prepare new ones as necessary, and promote them to the general public.

2. Progress of revisions, etc.

In FY 2024, we revised or newly drafted the following manuals. The revisions were reported and discussed at the meeting of the Committee on the Comprehensive Actions for Serious ADRs held on September 3, 2025 and were published in February 2026.

Author	Manual title	Category: New (newly prepared) or Revision
Japanese Society of Allergology	Anaphylaxis	Revision
	Angioedema (events not induced by nonsteroidal anti-inflammatory drugs)	Revision
	Urticaria/angioedema induced by nonsteroidal anti-inflammatory drugs (NSAIDs, antipyretic analgesics)	Revision
The Japanese Ophthalmological Society	Glaucoma	Revision
	Corneal opacity	Revision

The Japanese Respiratory Society	Interstitial pneumonia (pneumonitis, alveolitis, pulmonary fibrosis)	Revision

3. Plans for further revisions, etc.

In FY 2025, the following Manuals were revised or newly drafted based on the opinions of the Committee and the academic societies. The Manuals are scheduled to be published after being reported and discussed at the Committee on the Comprehensive Actions for Serious ADRs.

Author	Manual title	Category: New (newly prepared) or Revision
The Japan Society of Hepatology	Drug-induced liver injury	Revision
Japanese Circulation Society	Congestive cardiac failure	Revision
The Japanese Society of Child Neurology	Acute encephalopathy in children	Revision
The Japanese Dermatological Association	Stevens-Johnson syndrome	Revision
	Toxic epidermal necrolysis	Revision
	Drug-induced hypersensitivity syndrome	Revision

4. Increasing awareness of the Manuals

The newly prepared and revised manuals have been posted on the websites of the MHLW and PMDA, allowing not only healthcare professionals but also patients and their families to see these manuals (see [References] below).

Furthermore, in order to further disseminate the Manuals and to promote early detection and treatment of serious ADRs, we have been working on awareness-raising initiatives of the Manuals since FY2021.

In February 2026, we prepared a poster introducing the Manuals for “drug-related osteonecrosis of jaw/osteomyelitis of jaw” revised in March 2025 to patients. The electronic version of the poster can be found on the MHLW and PMDA websites.

An educational video about the Manuals has been prepared and published for patients and their families. You are encouraged to watch the video. (See [Reference] below)

重篤副作用疾患別対応マニュアル

医・歯・薬連携で薬剤関連顎骨壊死・顎骨骨髄炎を予防しよう！

―薬剤関連顎骨壊死・顎骨骨髄炎対応マニュアル　令和７年改定における２つの留意点(27 頁)―

悪い歯は放置しない

骨吸収抑制薬(ビスホスホネート製剤とデノスマブ製剤)を使用中の侵襲的歯科治療

▼

定期的歯科受診・治療メリットと発症リスクを勘案

原疾患の治療も大切

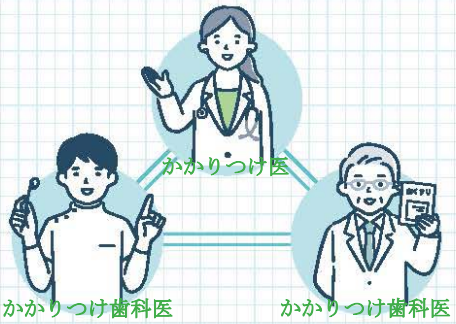
抜歯前の低用量の骨吸収抑制薬の取り扱い

▼

原則、予防的な休薬をせずに抜歯を提案
ハイリスク症例では、ごく短期間の休薬を完全に否定しない

剤関連顎骨壊死・顎骨骨髄炎予防のポイント　医・歯・薬　連携

- ☑ 正しい知識の説明(口腔ケア)と受診勧奨
- ☑ 骨吸収抑制薬開始前・後の定期的歯科受診
  (画像診断が重要)
- ☑ 情報共有
  (治療薬等の内容、症状、口腔管理など)



重篤副作用疾患別対応マニュアルを日常業務の中で活用してみよう！

〝歯やあごが痛い〟、〝歯のぐらつき〟、〝唇の周りがしびれる〟
などの症状に気づいたら医師、歯科医師、薬剤師等に相談するように患者支援

重篤副作用疾患別対応マニュアルはこちらからご覧いただけます。

厚生労働省 ひと、くらし、みらいのために Ministry of Health, Labour and Welfare

公益社団法人 日本口腔外科学会

This English version of PMDSI is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

5. In closing

Healthcare professionals are requested to continue to cooperate in the proper use of drugs by utilizing the Manuals and informing patients of them as necessary.

6. References

- MHLW website "Manuals for Management of Individual Serious ADRs"
  https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iyakuhin/topics/tp061122-1.html

- PMDA website "Manuals for Management of Individual Serious ADRs" (intended for healthcare professionals)
  https://www.pmda.go.jp/safety/info-services/drugs/adr-info/manuals-for-hc-pro/0001.html

- PMDA website "Manuals for Management of Individual Serious ADRs" (intended for patients/general population)
  https://www.pmda.go.jp/safety/info-services/drugs/adr-info/manuals-for-public/0001.html

- PMDA website introducing materials related to Manuals for Management of Individual Serious ADRs
  https://www.pmda.go.jp/safety/info-services/drugs/adr-info/manuals-for-public/0003.html

Previous articles introducing the "Initiative of Revision of the Manuals for Management of Individual Serious ADRs"
1. Pharmaceuticals and Medical Devices Safety Information No. 348
(https://www.mhlw.go.jp/file/06-Seisakujouhou-11120000-Iyakushokuhinkyoku/0000184551.pdf)
2. Pharmaceuticals and Medical Devices Safety Information No. 357
(https://www.mhlw.go.jp/content/11120000/000366073.pdf)
3. Pharmaceuticals and Medical Devices Safety Information No. 368

(https://www.mhlw.go.jp/content/11120000/000570642.pdf)
Previous articles introducing "Manuals for Management of Individual Serious ADRs"
1. Pharmaceuticals and Medical Devices Safety Information No. 393
(https://www.mhlw.go.jp/content/11120000/000961948.pdf)
2. Pharmaceuticals and Medical Devices Safety Information No. 402
(https://www.mhlw.go.jp/content/11120000/001118160.pdf)
3. Pharmaceuticals and Medical Devices Safety Information No. 407
(https://www.mhlw.go.jp/content/11125000/001222791.pdf)
4. Pharmaceuticals and Medical Devices Safety Information No. 419
(https://www.mhlw.go.jp/content/11125000/PMDSI_No419.pdf)

2.

The Survey Results on the Status of Acquisition, Communication, and Use of Drug Safety Information at Hospitals and Pharmacies and Desirable Directions

1. Introduction

The MHLW and the PMDA have been implementing safety measures, such as revision of PRECAUTIONS in package inserts, etc., based on the reported information on adverse reactions to cooperatively ensure proper use of drugs and medical devices. Information necessary for the implementation of safety measures has been provided by the MHLW, the PMDA, the pharmaceutical companies, etc. to medical institutions through various routes. It is important to properly communicate the information to the related parties so that they can use it in clinical practice

Since FY 2010, the PMDA has been conducting surveys to understand the status of acquisition, communication, and use of safety information at medical institutions, etc. and to consider measures to promote the use of safety information for the purpose of ensuring steady implementation of the safety measures taken and further patient safety.

In the survey in FY 2025, PMDA also conducted a survey targeting physicians to understand the status of use of drug safety information in medical practice while continuing the existing survey mainly targeting pharmacists as well as a follow-up survey on the status of acquisition of information in association with digitalization of package inserts and the status of utilization of RMP. This issue introduces results of surveys on the following matters and discussion of the results (desirable directions): 1) acquisition of information, 2) the status of understanding and use of risk communication tools such as the RMP, which was identified as an issue in the previous surveys, and 3) the status of use of GS1 barcodes.

2. Survey in FY2025

(1) Method and contents of the survey

Table 1 shows the period, method, main contents, etc. of the survey conducted in FY 2025.

The "Review Committee for the Survey on the Status of Acquisition, Communication, and Use of Drug Safety Information at Medical Institutions, etc." (Chairman: Nobuyuki Muroi, Director of Department of Pharmacy, Kobe City Medical Center General Hospital), which consists of experts on the operations of physicians and pharmacists and on drug information, was established within the PMDA to hear their opinions on the surveys.

Table 1. Outline of the Surveys

	Survey in hospitals	Survey in pharmacies
Period	June 16, 2025 to July 28, 2025	
Hospitals/pharmacies surveyed	40% of hospitals nationwide (3,248 institutions)	5% of pharmacies nationwide (3,146 institutions)
Respondent	Drug safety managers and physicians	Supervising pharmacists or DI personnel
Methods	- Survey forms were sent to the drug safety managers by mail - For the survey targeting physicians, drug safety managers were requested to distribute the URL of the website for the survey to physicians in their institution.	- Survey forms were sent to supervising pharmacists or DI personnel by mail.
	Multiple-choice or open-ended questions	
	Respondents either completed the web questionnaire or returned the paper questionnaire (Only web questionnaire is selectable for physicians)	
Main contents	- Means of acquiring and communicating drug safety information - The status of understanding and use of Risk Management Plan (RMP) and Manuals for Management of Individual Serious ADRs - The status of use of codes such as GS1 barcodes and data, etc.	

(2) Outline of survey respondent institutions

For the survey conducted in hospitals, 1,257 institutions (38.7%) responded to the questionnaire in the survey targeting drug safety managers (hereinafter referred to as "hospital survey") and 1,042 institutions responded to the questionnaire in the survey targeting physicians (hereinafter referred to as "physician survey"). In the survey conducted in pharmacies (hereinafter referred to as "pharmacy survey"), 2,351 institutions responded to the questionnaire (74.7%). Outline of the respondent institutions is shown in Figure 1.

Figure 1-1: Number of beds [Hospitals]

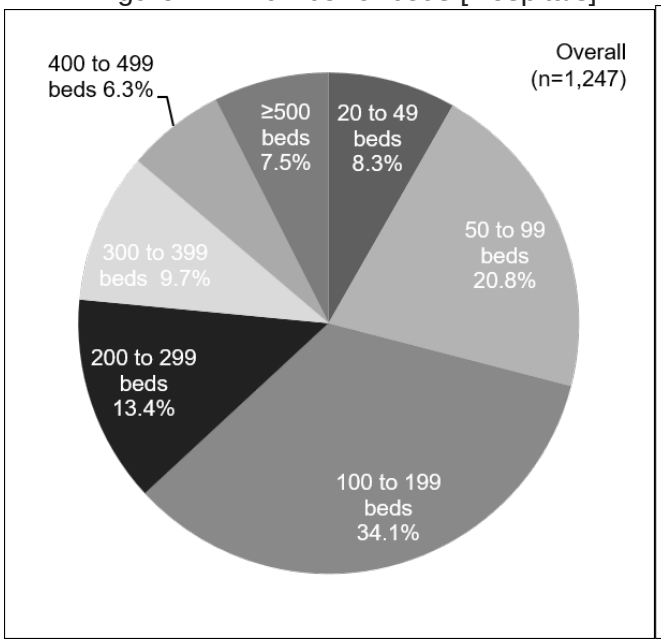


Figure 1-2: Number of beds [Physicians]

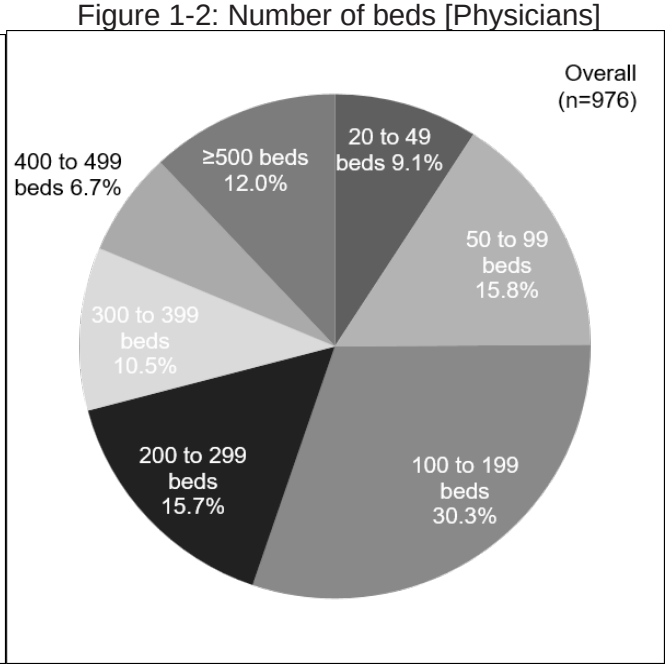
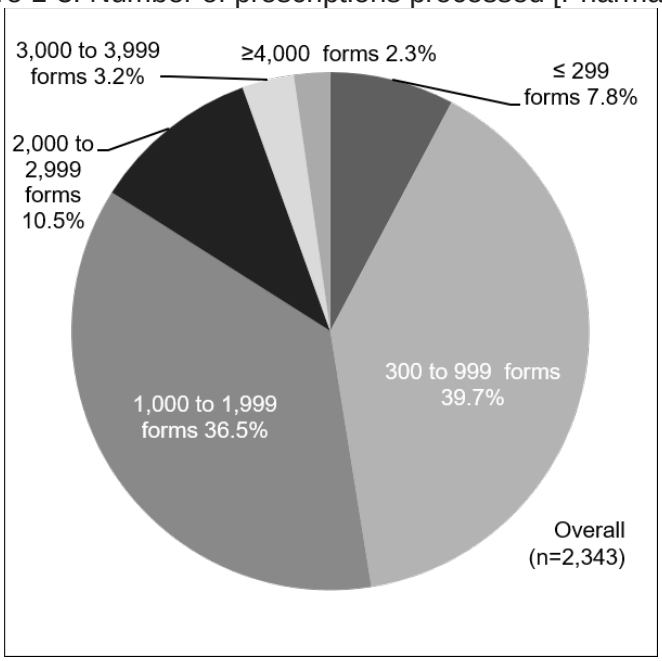


Figure 1-3: Number of prescriptions processed [Pharmacies]



*Number of prescriptions processed for May 2025 or for the most recent month

(3) Outline of survey results

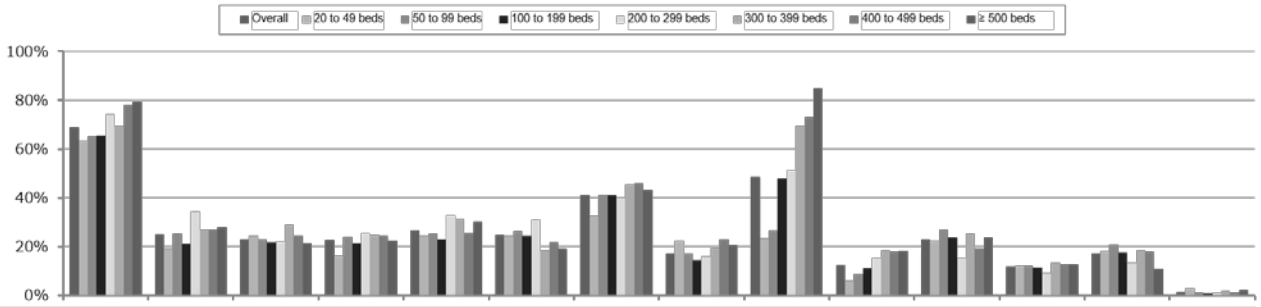
The outline of results of the current survey (the survey in FY2025) is as follows. The results of "the survey in FY2022" are presented as the results of "previous survey" for comparison. Since only valid responses are counted, the total number may differ depending on the graph.

1) Acquisition of the latest drug safety information

With the enforcement of the revised Pharmaceuticals and Medical Devices Act in August 2021, access to the PMDA website for electronic acquisition of information has become a basic means of browsing the latest package insert information. However, the previous survey was conducted during the period for transitional measures (until the end of July 2023).

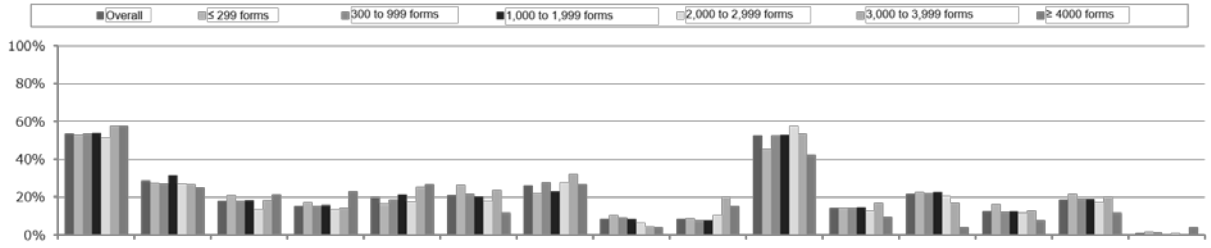
After the period for the transitional measures has ended, we investigated the means of browsing the latest package insert information (multiple choices allowed). The results showed that 68.8% of hospitals and 53.6% of pharmacies said that they would visit the "PMDA website," and 48.5% of hospitals and 52.6% of pharmacies said that they would use "their in-house system such as the electronic medical record system (receipt computer system in pharmacies)." Hospitals with a large number of beds tended to use "their in-house system such as the electronic medical record system" (Figure 2). In the physician survey, approximately half of the respondent physicians listed "In-house system such as electronic medical record system" as the source of information. In addition, the frequency of updating information was investigated in the institutions that listed in-house systems as a means of browsing package inserts. The result revealed that approximately 70% of the respondent institutions were updating the information at least once a month for both hospitals and pharmacies, suggesting that the latest information was accessed in the respondent institutions in general (Figure 3).

Figure 2-1: Means of browsing the latest package insert information (multiple choices allowed)
[Hospitals: by number of beds]



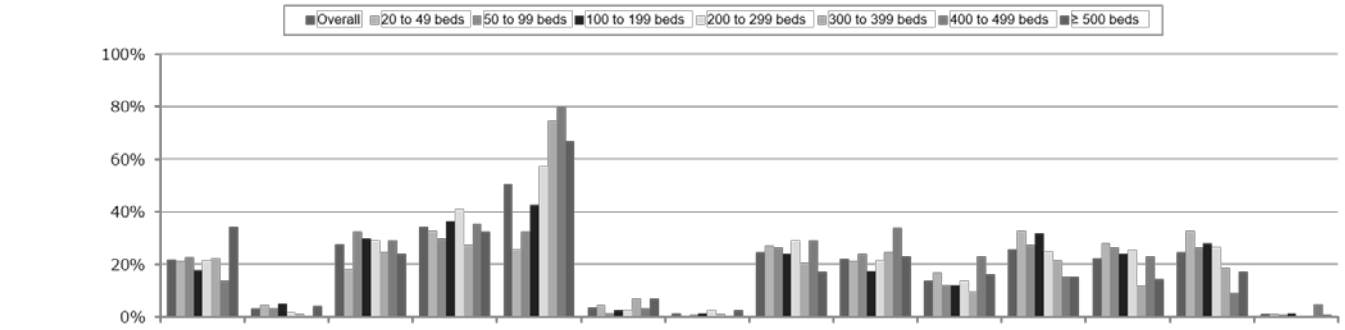
	Number of institutions (number of respondent institutions)	Website of the Pharmaceuticals and Medical Devices Agency (PMDA)	PMDA Medi-navi	Pharmaceuticals and Medical Devices Safety Information (issued by the Ministry of Health, Labour and Welfare)	Drug Safety Update (DSU, issued by The Federation of Pharmaceutical Manufacturers' Association of Japan)	Medical representatives (MRs) or marketing specialists (MS)	Direct mails (DM) from pharmaceutical companies	Websites of pharmaceutical companies	Website of drug wholesalers (drug information site)	In-house system such as electronic medical record system	Application for reading GS1 barcode such as Package insert-navi	Healthcare-related websites, e-mail delivery services, apps	Books	General search sites	Other
Overall	1,217	68.8 %	25.1 %	23.2 %	22.8 %	26.5 %	24.7 %	41.2 %	17.4 %	48.5 %	12.6 %	23.1 %	11.8 %	17.4 %	1.4 %
20 to 49 beds	98	63.3 %	19.4 %	24.5 %	16.3 %	24.5 %	24.5 %	32.7 %	22.4 %	23.5 %	6.1 %	22.4 %	12.2 %	18.4 %	3.1 %
50 to 99 beds	255	65.5 %	25.5 %	23.1 %	23.9 %	25.5 %	26.3 %	41.2 %	17.3 %	26.7 %	9.0 %	27.1 %	12.2 %	20.8 %	1.2 %
100 to 199 beds	412	65.5 %	21.1 %	21.8 %	21.6 %	23.1 %	24.5 %	41.0 %	14.6 %	47.8 %	11.2 %	23.8 %	11.4 %	17.7 %	1.0 %
200 to 299 beds	163	74.2 %	34.4 %	22.1 %	25.8 %	33.1 %	31.3 %	39.9 %	16.0 %	51.5 %	15.3 %	15.3 %	9.2 %	13.5 %	1.2 %
300 to 399 beds	118	69.5 %	27.1 %	28.8 %	24.6 %	31.4 %	18.6 %	45.8 %	19.5 %	69.5 %	18.6 %	25.4 %	13.6 %	18.6 %	1.7 %
400 to 499 beds	78	78.2 %	26.9 %	24.4 %	24.4 %	25.6 %	21.8 %	46.2 %	23.1 %	73.1 %	17.9 %	19.2 %	12.8 %	17.9 %	1.3 %
≥ 500 beds	93	79.6 %	28.0 %	21.5 %	22.6 %	30.1 %	19.4 %	43.0 %	20.4 %	84.9 %	18.3 %	23.7 %	12.9 %	10.8 %	2.2 %

Figure 2-2: Means of browsing the latest package insert information (multiple choices allowed)
[Pharmacies: by number of prescriptions processed]



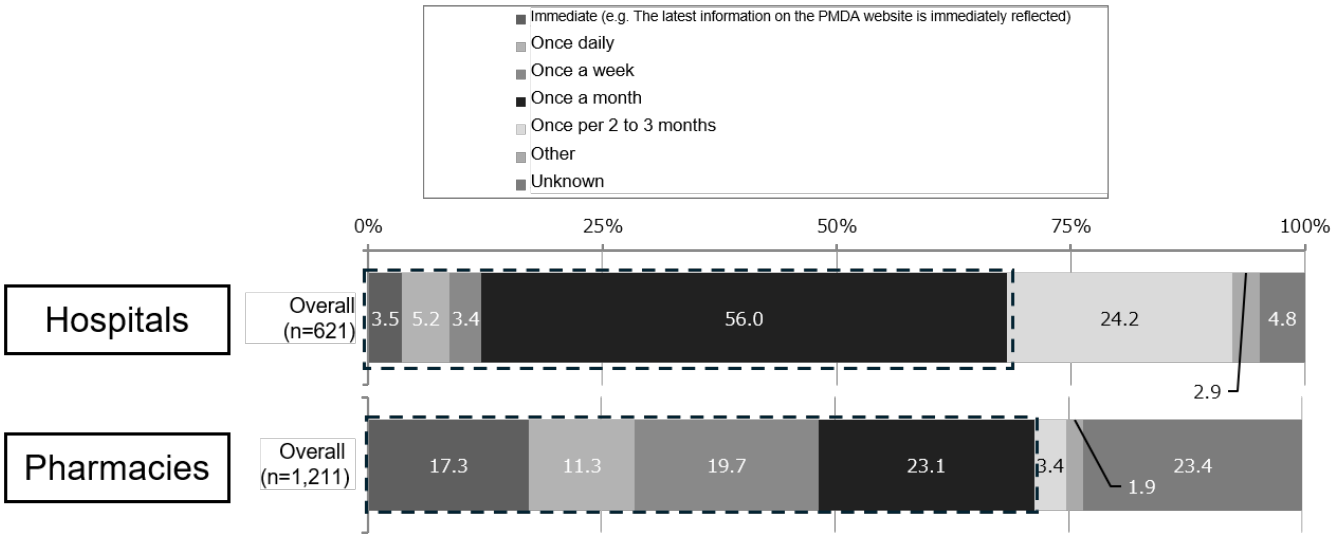
	Number of institutions (number of respondent institutions)	Website of the Pharmaceuticals and Medical Devices Agency (PMDA)	PMDA Medi-navi	Pharmaceuticals and Medical Devices Safety Information (issued by the Ministry of Health, Labour and Welfare)	Drug Safety Update (DSU, issued by The Federation of Pharmaceutical Manufacturers' Association of Japan)	Medical representatives (MRs) or marketing specialists (MS)	Direct mails (DM) from pharmaceutical companies	Websites of pharmaceutical companies	Website of drug wholesalers (drug information site)	Information from the head office and other departments that compile DI information (e-mail, paper, etc.)	In-house system such as receipt computer system	Application for reading GS1 barcode such as Package insert-navi	Healthcare-related websites, e-mail delivery services, apps	Books	General search sites	Other
Overall	2,196	53.6 %	28.8 %	17.9 %	15.5 %	19.7 %	20.9 %	25.9 %	8.3 %	8.5 %	52.6 %	14.2 %	21.5 %	12.4 %	18.9 %	1.0 %
≤ 299 forms	163	52.8 %	27.6 %	20.9 %	17.2 %	16.6 %	26.4 %	22.1 %	10.4 %	8.6 %	45.4 %	14.1 %	22.7 %	16.0 %	21.5 %	1.8 %
300 to 999 forms	876	53.5 %	27.3 %	17.8 %	15.3 %	18.6 %	21.6 %	28.0 %	9.0 %	7.6 %	52.6 %	14.2 %	21.9 %	12.1 %	18.9 %	1.5 %
1,000 to 1,999 forms	805	53.9 %	31.6 %	18.3 %	15.7 %	21.2 %	20.1 %	23.1 %	8.2 %	7.5 %	53.0 %	14.8 %	22.7 %	12.5 %	19.1 %	0.4 %
2,000 to 2,999 forms	229	51.5 %	27.1 %	13.5 %	13.5 %	17.5 %	17.9 %	27.9 %	6.6 %	10.5 %	57.6 %	12.7 %	20.5 %	11.8 %	17.0 %	0.9 %
3,000 to 3,999 forms	71	57.7 %	26.8 %	18.3 %	14.1 %	25.4 %	23.9 %	32.4 %	4.2 %	19.7 %	53.5 %	16.9 %	16.9 %	12.7 %	19.7 %	0.0 %
≥ 4000 forms	52	57.7 %	25.0 %	21.2 %	23.1 %	26.9 %	11.5 %	26.9 %	3.8 %	15.4 %	42.3 %	9.6 %	3.8 %	7.7 %	11.5 %	3.8 %

Figure 2-3: Means of browsing the latest package insert information (multiple choices allowed) [Physicians: by number of beds]



	Number of institutions (number of respondent institutions)	Website of the Pharmaceuticals and Medical Devices Agency (PMDA)	PMDA Medi-navi	Medical representatives (MRs)	Websites of pharmaceutical companies	In-house system such as electronic medical record system	Mailing list within a institution or related institutions	Application for reading GS1 barcode such as Package insert-navi	Healthcare-related websites, e-mail delivery services, apps	Websites and guidelines of academic societies	Articles	Other medical staff such as physicians and pharmacists	Books (paper, electronic)	General search sites	Other
Overall	976	21.7 %	3.4 %	27.8 %	34.3 %	50.5 %	3.6 %	1.3 %	24.7 %	22.0 %	13.8 %	25.9 %	22.5 %	24.5 %	1.0 %
20 to 49 beds	89	21.3 %	4.5 %	18.0 %	32.6 %	25.8 %	4.5 %	0.0 %	27.0 %	21.3 %	16.9 %	32.6 %	28.1 %	32.6 %	1.1 %
50 to 99 beds	154	22.7 %	3.2 %	32.5 %	29.9 %	32.5 %	1.3 %	0.6 %	26.6 %	24.0 %	12.3 %	27.3 %	26.6 %	26.6 %	0.6 %
100 to 199 beds	296	17.9 %	5.1 %	29.7 %	36.5 %	42.6 %	2.7 %	1.4 %	24.0 %	17.6 %	12.2 %	31.8 %	24.0 %	28.0 %	1.4 %
200 to 299 beds	153	21.6 %	2.0 %	29.4 %	41.2 %	57.5 %	2.6 %	2.6 %	29.4 %	21.6 %	13.7 %	24.8 %	25.5 %	26.8 %	0.0 %
300 to 399 beds	102	22.5 %	1.0 %	24.5 %	27.5 %	74.5 %	6.9 %	1.0 %	20.6 %	24.5 %	9.8 %	21.6 %	11.8 %	18.6 %	0.0 %
400 to 499 beds	65	13.8 %	0.0 %	29.2 %	35.4 %	80.0 %	3.1 %	0.0 %	29.2 %	33.8 %	23.1 %	15.4 %	23.1 %	9.2 %	4.6 %
≥ 500 beds	117	34.2 %	4.3 %	23.9 %	32.5 %	66.7 %	6.8 %	2.6 %	17.1 %	23.1 %	16.2 %	15.4 %	14.5 %	17.1 %	0.9 %

Figure 3: Frequency of updating drug information in systems such as electronic medical record systems/receipt computer systems



2) Status of understanding and use of risk communication tools such as RMP

In order to help healthcare professionals understand that each risk communication tool is useful for understanding of risks of drugs in advance and appropriate follow-up after drug administration including early detection of adverse reactions as well as to promote use of these tools, the PMDA has disseminated the information on these tools by awareness raising activities including giving lectures and setting exhibition booths at various academic conferences and publishing articles in journals, etc. and especially for RMP, prepared awareness raising materials and e-learning videos.

In the current survey, 60.6% of hospitals (54.4% in the previous survey) and 75.5% of pharmacies (25.2% in the previous survey) answered that they understood what the RMP was (understand well or understand to some extent). The result in the hospital survey was not significantly different from the

previous surveys, but the results in the pharmacies showed a considerable improvement (Figure 4). The same trend was observed in the change in the status of use of RMP and RMP materials in comparison to the previous survey (Table 2). In an investigation of the level of awareness of RMP in the physician survey, the percentage of the physicians who answered that they "know" RMP was 8.3%.

The institutions and physicians answering that they have never used RMP or RMP materials were asked about the reason. They have never used RMP or RMP materials because they have had no opportunity to use them or because other information sources such as package inserts and interview forms have been sufficient or because they did not know how to use them specifically (Table 3).

The status of understanding and use of RMP shown in the current pharmacy survey had considerably changed compared to the previous survey. When focusing on the examples of actual use of RMP, there was no major difference in comparison to the previous survey, but the proportion of institutions that have used RMP for assessment of drugs linked to onset of adverse drug reactions had decreased (Table 4). The examples of actual use were reviewed by the level of understanding of RMP. As a result, use for assessment of drugs linked to onset of adverse drug reactions was ranked high in the institutions that well understand what RMP is (Figure 5).

Figure 4: The status of understanding of RMP

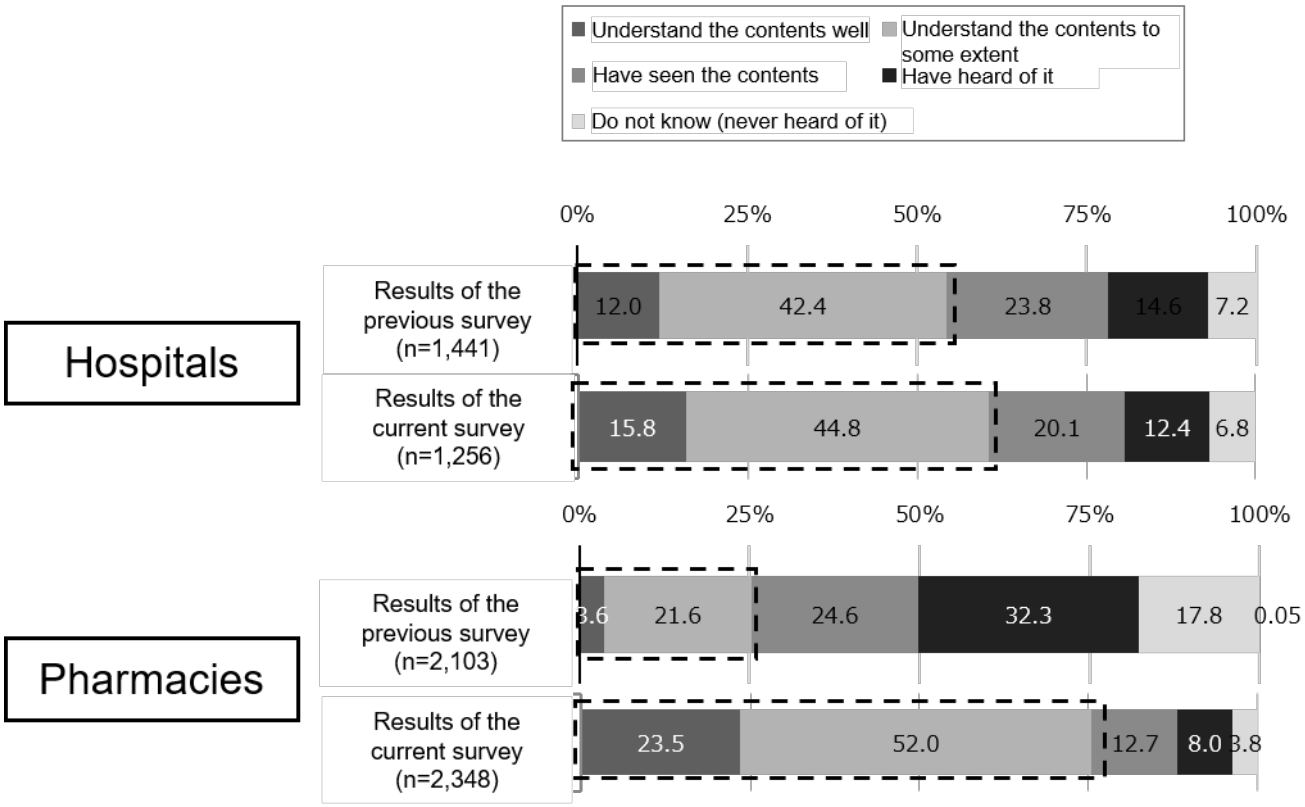


Table 2: Status of use of RMP/RMP materials at institutions that answered that they well understand what RMP is

(The figures in parentheses represent the results of the previous survey.)

	Have used RMP	Have used RMP materials
Hospitals	62.8 % (61.2 %)	57.5 % (53.7 %)
Pharmacies	77.8 % (44.3 %)	87.1 % (38.2 %)

Table 3: Reason for having not used RMP (multiple choices allowed)

[Hospitals: Drug safety manager]

1. Other information sources such as package inserts and interview forms have been sufficient (47.2%).
2. There is no opportunity to use RMP (42.7%).
3. Do not know how to use RMP specifically (37.3%)

[Hospitals: Physicians] * Reasons for having not used RMP and RMP materials in physicians

1. There is no opportunity to use RMP and RMP materials (55.0%).
2. Other information sources such as package inserts and interview forms have been sufficient (30.0%).
3. Do not know how to use RMP and RMP materials specifically (10.0%)

There is no time to read RMP and RMP materials (10.0%).

The contents of the materials are difficult for patients (10.0%).

There is no difference in the contents from other materials than RMP materials (10.0%).

[Pharmacies]

1. There is no opportunity to use RMP (40.9%).
2. Other information sources such as package inserts and interview forms have been sufficient (36.7%).
3. Do not know how to use RMP specifically (34.7%)

Table 4: Examples of actual use of RMP in pharmacies (multiple choices allowed)

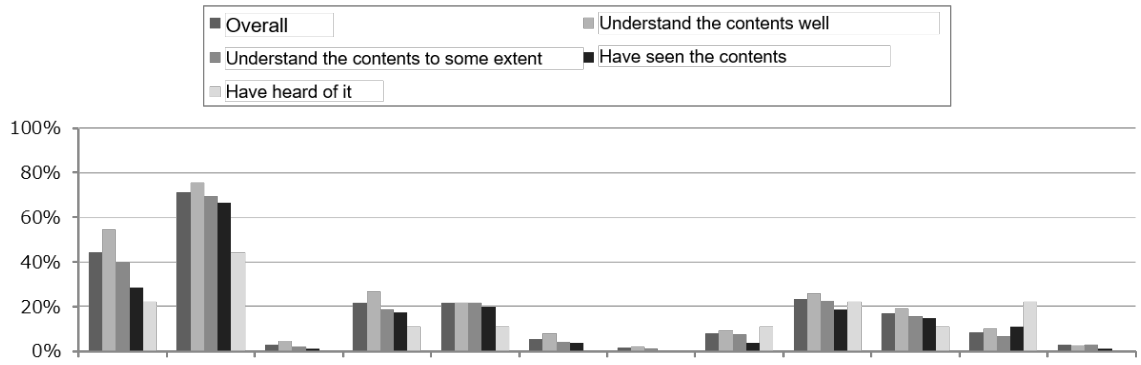
[Current survey]

1. For grasping possible risks when adopting new drugs (71.2%)
2. For grasping the overview of safety specifications, pharmacovigilance plan, and risk minimization plan (44.3%)
3. When a notification of release of a new RMP was received via the PMDA Medi-Navi (23.3%)
4. For responding to inquiries from physicians (hospitals/clinics), etc. (21.6%)
5. For assessment of drugs linked to onset of adverse drug reactions (21.5%)

[Previous survey]

1. For grasping possible risks when adopting new drugs (69.8%)
2. For grasping the overview of safety specifications, pharmacovigilance plan, and risk minimization plan (42.1%)
3. For assessment of drugs linked to onset of adverse drug reactions (35.7%)
4. For responding to inquiries from physicians (hospitals/clinics), etc. (31.9%)
5. When a notification of release of a new RMP was received via the PMDA Medi-Navi (27.7%)

Figure 5: Example of actual use of RMP [Pharmacies: by the level of understanding of RMP]



	Number of institutions (number of respondent institutions)	For grasping the overview of safety specifications, pharmacovigilance plan, and risk minimization plan	For grasping possible risks when adopting new drugs	For grasping the schedule of post-marketing surveillance, etc.	For assessment of drugs linked to onset of adverse drug reactions	For responding to inquiries from physicians (hospitals/clinics), etc.	For preparing the adverse reaction monitoring plan	For preparing internal news for pharmacies, etc.	For holding a study meeting or workshop	When a notification of release of new RMP was received via the PMDA Medi-Navi	When a notification of update of RMP was received via the PMDA Medi-Navi	When descriptions of RMP are found in interview forms	Other
Overall	1,461	44.3 %	71.2 %	2.9 %	21.5 %	21.6 %	5.5 %	1.5 %	8.1 %	23.3 %	16.9 %	8.3 %	2.7 %
Understand the contents well	506	54.7 %	75.5 %	4.7 %	26.9 %	21.7 %	8.1 %	2.2 %	9.3 %	25.9 %	19.2 %	10.3 %	2.4 %
Understand the contents to some extent	865	39.9 %	69.4 %	2.1 %	18.8 %	21.8 %	4.3 %	1.3 %	7.7 %	22.3 %	15.8 %	6.7 %	3.0 %
Have seen the contents	81	28.4 %	66.7 %	1.2 %	17.3 %	19.8 %	3.7 %	0.0 %	3.7 %	18.5 %	14.8 %	11.1 %	1.2 %
Have heard of it	9	22.2 %	44.4 %	0.0 %	11.1 %	11.1 %	0.0 %	0.0 %	11.1 %	22.2 %	11.1 %	22.2 %	0.0 %

The status of understanding/use of Drug Guide for Patients was also investigated and the result revealed that the percentage of institutions that understand the contents (understand well or understand to some extent) was 42.0% (40.7% in the survey before the previous one [FY 2017]) for hospitals and 35.6% (28.0% in the survey before the previous one) for pharmacies. Of these, 59.4% of the hospitals (68.4% in the survey before the previous one) said that they have used Drug Guide for Patients in their operations and 65.6% of the pharmacies (68.3% in the survey before the previous one) said that they have used it for their operation, showing that there was no change in the status of understanding and use of Drug Guide for Patients compared to the survey before the previous one. In the physician survey, the percentage of the physicians who answered that they "know" Drug Guide for Patients was 14.0%.

3) Status of use of GS1 barcode

In August 2021, safety information such as electronic package inserts became accessible using GS1 barcodes. In December 2022, the Pharmaceuticals and Medical Devices Act made GS1 barcode labeling on the package (sales packaging unit) of products mandatory for the purpose of improving the traceability. In addition to these situations, the scheduled construction of a product database *[1] and the mandatory registration of GS1 codes in this database are expected to improve medical safety even more and promote efficient utilization of information. The current survey revealed that 59.0% of hospitals and 71.6% of pharmacies have used GS1 barcodes in their operations. The percentage of hospitals that have used GS1 barcodes tended to be higher in hospitals with larger numbers of beds.

Examples of actual use of GS1 barcodes included inventory management (80.6% of the hospitals and 77.9% of the pharmacies) and replenishment of drugs (52.6% of the hospitals and 43.7% of the pharmacies).

[1] Official product database to be established starting in FY 2026. This database is intended to contribute to promotion of DX in pharmaceutical, medical devices, etc. distribution for improvement in the medical safety. The PMDA has taken the initiative.

Figure 6: Status of use of GS1 barcodes

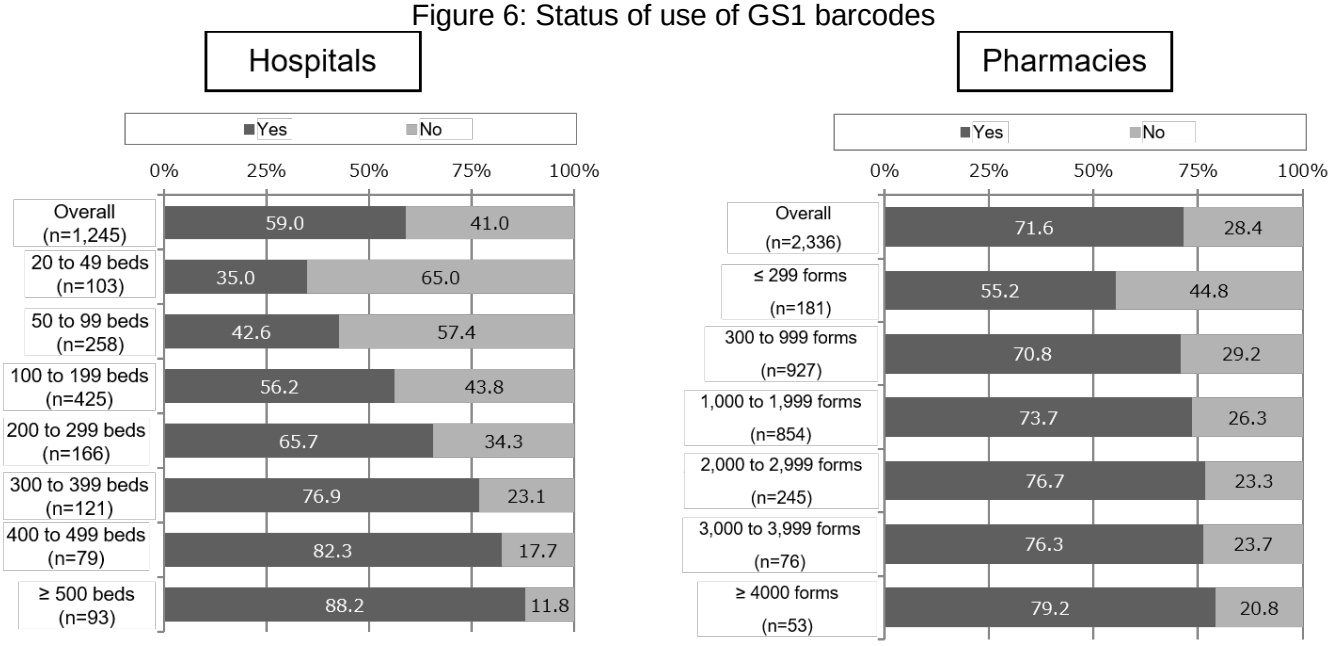


Table 5: Examples of actual use of GS1 barcodes (multiple choices allowed)

[Hospitals: Drug safety manager]
1. Inventory management (e.g. order/delivery/shipping/inventory check/expiry date check) (80.6%)
2. Replenishment of drugs (e.g., filling medicine shelves, etc./filling up automatic medicine packaging machines) (52.6%)
3. Stockpiling tablets, topical drugs, etc. (25.4%)

[Pharmacies]
1. Inventory management (e.g. order/delivery/shipping/inventory check/expiry date check) (77.9%)
2. Inspection (47.3%)
3. Replenishment of drugs (e.g., filling medicine shelves etc./filling up automatic medicine packaging machines, etc.) (43.7%)

(4) Discussion (desirable directions)

- Creation of correct understanding

The PMDA has been performing awareness raising activities for risk communication tools, including RMP, but found no marked effect in the results of the current survey. The pharmacy survey demonstrated an improvement in the status of understanding and use of RMP, but this improvement may be partly associated with the addition of a fee for evaluation related to RMP to the dispensing fee in FY 2024. On the other hand, examples of actual use of RMP and reasons for not using RMP suggest the necessity of continuously raising the level of understanding of RMP. It is considered necessary to review the actual use status of RMP in actual clinical practice in future surveys.

Low awareness of RMP and Drug Guide for Patients among physicians was also demonstrated, indicating that it is considered important to not only continue existing PR activities but also create correct understanding of characteristics and importance of safety information provided by the PMDA in an early stage. Thus, efforts should be made to foster such recognition in healthcare professional education settings, thereby promoting practical use of these materials.

With the revision of the Pharmaceuticals and Medical Devices Act, the operation policy for RMP will be changed so that necessary pharmacovigilance activities and risk minimization plan (preparation of materials for healthcare professionals and patients, etc.) will be set according to the degree of risks regardless of whether or not the product is a new drug and its reexamination period is ongoing. The revision will be enforced by May 2027. We will carefully disseminate information including new concepts of and operation policy for RMP to make them easy to understand in medical settings.

- Creation of contents that promote active utilization

Regarding risk communication tools that are not actively utilized, it is considered necessary to

investigate the causes in detail and review the contents of these tools and method of the provision according to the causes. Regarding the Drug Guide for Patients, "Drug Guide for Patients Review Meeting", which has already been established at the PMDA, has discussed the positioning, contents and provision method of the Drug Guide for Patients and has initiated activities to improve the status of understanding and use of this material.

- **Smooth access to information**

Linking systems that are routinely used in institutions such as electronic medical record systems with safety information on the PMDA website is considered to promote improvement in awareness/utilization of each risk communication tool even more. In addition, it is also considered necessary to discuss measures to be taken for more active utilization, such as organizing the method of posting information on the PMDA website and organizing issues arising when private companies utilize information on the PMDA website to operate their information provision services.

- **Creation of an organizational structure that promotes the utilization**

Proactively sharing and providing obtained information for not only pharmacists but also other professionals, including physicians, will contribute to improvement in the level of understanding and utilization of such information across the medical settings. For this reason, it is desirable to establish a system that enables information to be surely communicated through such efforts as improving procedures so as to allow other professionals to utilize the information.

Regarding use of GS1 barcodes, in light of the future prospect, it is desirable that the significance of its utilization will be understood and its utilization will be expanded.

In order to further promote utilization of drug safety information, it is important for both the information provider and the information users to summarize their challenges and examine measures for establishing a system for utilization of the information.

3. In closing

While this article introduces some results of the survey conducted in FY 2025, the PMDA website provides other survey results and reports as well. We encourage you to utilize the results of this survey and the desirable directions to properly acquire, communicate, and use drug safety information.

We would like to ask for your continued understanding and cooperation in the enhancement of safety measures for drugs, appropriate follow-up after drug administration, and promotion of proper use of drugs to further ensure patient safety.

[Survey on the status of acquisition, communication, and use of drug safety information at medical institutions, etc.]
https://www.pmda.go.jp/safety/surveillance-analysis/0010.html (only in Japanese)

< Reference information >

- The risk communication tools such as the RMP covered in the current surveys are available on the following pages of the PMDA website. Use of the risk communication tools is encouraged for the safety management of drugs, etc. at your facilities when making decisions on formulary adoption or giving medication guidance to patients.

[Risk Management Plan: RMP]
https://www.pmda.go.jp/safety/info-services/drugs/items-information/rmp/0002.html

[The Manuals for Management of Individual Serious Adverse Drug Reactions (intended for healthcare professionals)]
https://www.pmda.go.jp/safety/info-services/drugs/adr-info/manuals-for-hc-pro/0001.html(only in Japanese)

[PMDA Medical Safety Information]
https://www.pmda.go.jp/safety/info-services/medical-safety-info/0001.html

[Drug Guide for Patients]
https://www.pmda.go.jp/safety/info-services/drugs/items-information/guide-for-patients/0001.html(only in Japanese)

- Registration to the PMDA Medi-navi, a useful tool for information collection, can be made on the following website. Registration and use of the PMDA Medi-navi is strongly encouraged.

[PMDA Medi-navi]
https://www.pmda.go.jp/safety/info-services/medi-navi/0007.html (only in Japanese)

Registration to both the PMDA Medi-navi and the service to create My Drug List for Safety Update (an optional function) is required to use the bulk download function of package inserts of prescription drugs.
[Service to create My Drug List for Safety Update and bulk download service for package inserts of prescription drugs]
https://www.pmda.go.jp/safety/info-services/medi-navi/0012.html (only in Japanese)

- The PMDA has developed a system that allows access to safety information on the PMDA website through GS1 barcodes and YJ codes, and released the specifications. You are encouraged to use these codes. The detailed explanation is provided in the page accessed via the following.

https://www.pmda.go.jp/safety/info-services/0003.html

3.

Important Safety Information

Regarding the revision of PRECAUTIONS of package inserts of drugs in accordance with the Notification dated April 21,2026, this section will present the details of important revisions as well as the case summary serving as the basis for these revisions.

1 Regorafenib hydrate

Brand name (name of company)	Stivarga tablets 40 mg (Bayer Yakuhin, Ltd.) Stivarga tablets 40 mg (Bayer Yakuhin, Ltd.)
Therapeutic category	Other antitumor agents
Indications	○ Unresectable advanced or recurrent colorectal cancer ○ Gastrointestinal stromal tumor which has progressed after cancer chemotherapy ○ Unresectable hepatocellular carcinoma which has progressed after cancer chemotherapy

PRECAUTIONS (A revised description is underlined.)

11.1 Clinically Significant Adverse Reactions (newly added)	Hyperammonaemia Hyperammonaemia may occur in the absence of hepatic dysfunction. If consciousness disturbed is observed, measurement of ammonia levels should be considered
Reference	Number of cases (for which a causal relationship between the drug and the event is reasonably possible) collected in the PMDA's safety database† 7 in Japan (No patient mortalities) Number of patients using the drug as estimated by the MAH during the previous 1-year period: approximately 4,620 Japanese market launch: Stivarga tablets 40 mg: May 2013

Case summary

No.	Patient		Daily dose/ Administration duration	Adverse reactions	
	Sex/ age	Reason for use (complication)		Clinical course and treatment	
1	Male 70s	Rectal cancer (metastases to pelvis, metastases to liver, ventricular extrasystoles, diabetes mellitus, drug allergy)	80 mg 2 days ↓ Discontinuation	Hyperammonaemia	
				1 day before administration	NH3 levels were not measured.
				Day of administration	Administration of regorafenib was started for rectal cancer.
				Day 1 of administration	Tendency toward somnolence was observed, and the patient started answering "OK" consistently to all questions.
				Day 2 of administration (day of discontinuation)	Hyperammonaemia (CTCAE grade 3, NH3 level 201), hepatic failure (CTCAE grade 3), depressed level of consciousness (CTCAE grade 2), disturbance in attention (CTCAE grade 2), and memory impairment (CTCAE grade 1) occurred. Administration of regorafenib was discontinued. Tendency toward somnolence persisted. The patient became unable to eat without assistance and therefore visited the hospital. The patient could hardly walk because of weakness in the whole body.
				1 day after discontinuation	Treatment was started with lactulose and an amino acid preparation for hepatic failure.
				3 days after discontinuation	Hyperammonaemia and hepatic failure were resolving. Depressed level of consciousness, disturbance in attention, and memory impairment had resolved.
				9 days after discontinuation	NH3 level was 116.

Laboratory test values

Test item (unit)	1 day before administration	Day 2 of administration (day of discontinuation)	9 days after discontinuation
APTT (S)	-	35.5	-
ALT (U/L)	19	21	20
AST (IU/L)	51	46	36
NH3 (mcg/Dl)	-	201	116
ALB (g/Dl)	3.2	3.3	-
ALP (U/L)	-		364
T-Bil (mg/Dl)	1.1	1.6	1
LDH (U/L)	474	496	399
FDP/D-dimer (mcg/mL)	-	24.3	-
GGT (U/L)	66	-	96

Concomitant drugs: rabeprazole sodium, alogliptin benzoate, magnesium oxide, mosapride citrate hydrate, daikenchuto

4.

Revisions of PRECAUTIONS (No. 369)

This section provides details of the revisions of PRECAUTIONS and brand names of drugs that have been revised in accordance with the Notifications dated April 21, 2026.

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1 Other agents affecting digestive organs, agents affecting metabolism, n.e.c. (not elsewhere classified)

(1) Infliximab (genetical recombination)
(2) Infliximab (genetical recombination) [Infliximab Biosimilar 1]
(3) Infliximab (genetical recombination) [Infliximab Biosimilar 2]
(4) Infliximab (genetical recombination) [Infliximab Biosimilar 3]
(5) Etanercept (genetical recombination)
(6) Etanercept (genetical recombination) [Etanercept Biosimilar 1]
(7) Etanercept (genetical recombination) [Etanercept Biosimilar 2]

Brand name	(1) (2), (3), (4) Remicade for I.V. Infusion 100 (Tanabe Pharma Corporation) and the other biosimilars (5) (6) (7) Enbrel 10 mg for S.C. Injection, 25 mg for S.C. Injection, Enbrel 25 mg PEN 0.5 mL for S.C.Injection, 50 mg Pen 1.0 mL for S.C. Injection, 25 mg Syringe 0.5 mL for S.C.Injection, 50 mg Syringe 1.0 mL for S.C.Injection, 25 mg Syringe 0.5 mL for S.C.CLICWISE use, 50 mg Syringe 1.0 mL for S.C.CLICWISE use (Pfizer Japan Inc.), and the other biosimilars
11. ADVERSE REACTIONS **11.1 Clinically Significant Adverse Reactions** **(newly added)**	Autoimmune hepatitis

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2 Calcium compounds and preparations

Calcium chloride hydrate (injections excluding those indicated for electrolyte correction in electrolyte replacement fluids)

Brand name	Otsuka Calcium Chloride Injection 2% (Otsuka Pharmaceutical Factory, Inc.), Calcium Chloride Injection 2% "NP" (Nipro Corporation)
2. CONTRAINDICATIONS **(This drug is contraindicated to the following patients.)**	(Deleted)

10. INTERACTIONS

(Deleted)

10.1 Contraindications for Co-administration (Do not co-administer with the following.)

10.2 Precautions for Co-administration (This drug should be administered with caution when co-administered with the following.) (newly added)

Drugs	Signs, symptoms, and treatment	Mechanism/risk factors
Cardiac glycosides Metildigoxin Digoxin Deslanoside	This drug may enhance the effect of cardiac glycosides to induce toxic symptoms such as bradycardia, ventricular extrasystoles, atrioventricular block, and ventricular tachycardia. Cardiac arrest may occur. Co-administration with these drugs should be avoided except in cases where the co-administration is considered absolutely necessary for treatment. If co-administration is inevitable, monitoring by electrocardiography, etc. should be performed to take actions when arrhythmia occurs. In addition, avoid using this drug in such a way as to rapidly increase calcium concentration.	Calcium enhances cardiac contractility increasing the effect of cardiac glycosides.

3 Calcium compounds and preparations

Calcium gluconate hydrate

Brand name Calcicol Injection 8.5% 5 mL, 10 mL (Nichi-Iko Pharmaceutical Co., Ltd.)

2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) (Deleted)

10. INTERACTIONS (Deleted)

10.1 Contraindications for Co-administration (Do not co-administer with the following.)

10.2 Precautions for Co-administration (This drug should be administered with caution when co-administered with the following.) (newly added)

Drugs	Signs, symptoms, and treatment	Mechanism/risk factors
Cardiac glycosides Metildigoxin Digoxin Deslanoside	This drug may enhance the effect of cardiac glycosides to induce toxic symptoms such as bradycardia, ventricular extrasystoles, atrioventricular block, and ventricular tachycardia. Co-administration with these drugs should be avoided except in cases where the co-administration is considered absolutely necessary for treatment. If co-administration is inevitable, monitoring by electrocardiography, etc. should be performed to take actions when arrhythmia occurs. In addition, avoid using this drug in such a way as to rapidly increase calcium concentration.	Calcium enhances cardiac contractility increasing the effect of cardiac glycosides.

4 Other antitumor agents

Avelumab (genetical recombination)

Brand name	Bavencio intravenous infusion 200 mg (Merck Biopharma Co., Ltd)
11. ADVERSE REACTIONS	Severe skin disorder
11.1 Clinically Significant Adverse Reactions (newly added)	Severe skin disorders such as toxic epidermal necrolysis (TEN) may occur. Pemphigoid may occur. If blisters, erosion, etc. are observed, a dermatologist should be consulted.

5 Other antitumor agents

Regorafenib hydrate

Brand name	Stivarga tablets 40 mg (Bayer Yakuhin, Ltd.)
11. ADVERSE REACTIONS	Hyperammonaemia
11.1 Clinically Significant Adverse Reactions (newly added)	Hyperammonaemia may occur in the absence of hepatic dysfunction. If consciousness disturbed is observed, measurement of ammonia levels should be considered.

5.

List of Products Subject to Early Post-marketing Phase Vigilance

(As of March 31, 2026)

◎: Products for which EPPV was initiated on March 1, 2026 or later

	Nonproprietary name / Brand name	Name of the MAH	Date of EPPV initiation
◎	Vorasidenib citric acid hydrate / Voranigo Tablets 10 mg, 40 mg	NIHON SERVIER CO. LTD.	March 30, 2026
◎	Luseogliflozin hydrate / Lusefi OD film 2.5 mg, Lusefi tablets 2.5 mg, 5 mg	Taisho Pharmaceutical Co., Ltd.	March 23, 2026
◎	Linzagolix choline / Yselty Tablets 100 mg	Kissei Pharmaceutical CO., LTD.	March 19, 2026
◎	Zuranolone / Zurzuvae Capsules 30 mg	Shionogi & Co.,Ltd.	March 19, 2026
◎	Sebetralstat / Ekterly Tablets 300 mg	KalVista Pharmaceuticals Ltd.	March 18, 2026
◎	Tafasitamab (genetical recombination) / Minjuvi for intravenous infusion 200 mg	Incyte Biosciences Japan G.K.	March 18, 2026
◎	Tagraxofusp (genetical recombination) / Elzonris I.V. Injection 1000 μg	Nippon Shinyaku Co., Ltd.	March 18, 2026
◎	Retifanlimab (genetical recombination) / Zynyz for Intravenous Infusion 500 mg	Incyte Biosciences Japan G.K.	March 18, 2026
◎	Sepiapterin / Sephience Granules 250 mg, 1000 mg	PTC Therapeutics K.K.	March 18, 2026
◎	Amivantamab (genetical recombination)/Vorhyaluronidase alfa (genetical recombination) / Rybrofaz Combination Subcutaneous Injection	Janssen Pharmaceutical K.K.	March 18, 2026
◎	Mosunetuzumab (genetical recombination) / Lunsumio for Intravenous Infusion 5 mg, 45 mg	Chugai Pharmaceutical CO., LTD.	March 18, 2026
◎	Belantamab mafodotin (genetical recombination) / Blenrep for I.V. infusion 100 mg	GlaxoSmithKline K.K.	March 18, 2026

	Nonproprietary name Brand name	Name of the MAH	Date of EPPV initiation
	Vonicog alfa (genetical recombination) Vonvendi Intravenous 1300	Takeda Pharmaceutical Company Limited	February 19, 2026
	Tezepelumab (genetical recombination) *1 Tezspire Subcutaneous Injection 210 mg Syringe, Tezspire Subcutaneous Injection 210 mg Pen	AstraZeneca K.K.	February 19, 2026
	Adrenaline neffy nasal spray 1 mg, 2 mg	Alfresa Pharma Corporation	February 12, 2026
	Cantharidin Ycanth topical solution 0.71%	Torii Pharmaceutical CO., LTD.	February 9, 2026
	Diazepam Spydia Nasal Spray 5 mg, 7.5 mg, 10 mg	Aculys Pharma, Inc.	December 24, 2025
	Finerenone *2 Kerendia tablets 10 mg, 20 mg	Bayer Yakuhin, Ltd.	December 22, 2025
	Odevixibat hydrate Bylvay Granules 200 μg, 600 μg	IPSEN Co., Ltd	December 18, 2025
	Rimegepant sulfate hydrate Nurtec OD Tablets 75 mg	Pfizer Japan Inc.	December 16, 2025
	Midazolam Dormicum syrup 2 mg/mL	Maruishi Pharmaceutical Co., Ltd.	November 27, 2025
	Avacincaptad pegol sodium Izervay for intravitreal injection 20 mg/mL	Astellas Pharma Inc.	November 27, 2025
	Vornorexant hydrate Vorzzz tablets 2.5 mg, 5 mg, 10 mg	Taisho Pharmaceutical Co., Ltd.	November 27, 2025
	Chenodeoxycholic Acid *3 Fujichenon granular tablets 125	Fujimoto Pharmaceutical Corporation	November 21, 2025
	Bempedoic Acid Nexletol tablets 180 mg	Otsuka Pharmaceutical Co., Ltd.	November 21, 2025
	Repotrectinib *4 Augtyro capsules 40 mg, 160 mg	Bristol-Myers Squibb K.K.	November 20, 2025
	Inebilizumab (genetical recombination) *5 Uplizna for intravenous infusion 100 mg	Tanabe Pharma Corporation	November 20, 2025
	Gallium (68Ga) gozetotide Locametz kit	Novartis Pharma K.K.	November 12, 2025
	Lutetium (177Lu) vipivotide tetraxetan Pluvicto injection	Novartis Pharma K.K.	November 12, 2025
	Taletrectinib adipate Ibtrozi capsules 200 mg	Nippon Kayaku Co., Ltd.	November 12, 2025
	Zongertinib Hernexeos tablets 60 mg	Nippon Boehringer Ingelheim Co., Ltd.	November 12, 2025

Nonproprietary name Brand name		Name of the MAH	Date of EPPV initiation
	Nusinersen Sodium Spinraza intrathecal injection 28 mg, 50 mg	Biogen Japan Ltd.	November 12, 2025
	Selumetinib Sulfate Koselugo granules 5 mg, 7.5 mg	Alexion Pharma Godo Kaisha	November 12, 2025
	Nipocalimab (genetical recombination) Imaavy intravenous infusion 1200 mg	Janssen Pharmaceutical K.K.	November 12, 2025
	Palopegteriparatide Yorvipath subcutaneous injection 168 μg pen, 294 μg pen, 420 μg pen	Teijin Pharma Limited	November 6, 2025
	Gallium (68Ga) chloride GalliaPharm 68Ge/68Ga generator	Eckert & Ziegler Radiopharma GmbH (Oversee products designated MAH) Novartis Pharma K.K.	November 5, 2025
	Remimazolam besilate *6 Anerem 20 mg for I.V. injection	Mundipharma K.K.	November 4, 2025
	Pneumococcal 21-valent Conjugate Vaccine (joint component of nontoxic diphtheria toxin derivatives) Capvaxive for intramuscular injection syringes	MSD K.K.	October 29, 2025
	Sepetaprost Setaneo ophthalmic solution 0.002%	Santen Pharmaceutical Co., Ltd.	October 23, 2025

*1 Chronic rhinosinusitis with nasal polyps (limited to patients with inadequate response to existing treatments)
*2 Chronic cardiac failure, only limited to patients receiving standard treatment for chronic heart failure
*3 Cerebrotendinous xanthomatosis
*4 NTRK fusion gene-positive advanced or recurrent solid tumor
*5 Suppression of relapse in IgG4-related diseases
*6 Sedation during gastrointestinal endoscopy