Pharmaceuticals and Medical Devices Safety Information

No. 421 July 2025

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This *Pharmaceuticals and Medical Devices Safety Information (PMDSI)* publication is issued reflective of safety information collected by the Ministry of Health, Labour and Welfare (MHLW). 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) web page (https://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0002.html) and on the MHLW website (https://www.mhlw.go.jp/, only in Japanese).

Available information is listed here

Access to the latest safety information is available via the PMDA Medi-navi.

The PMDA Medi-navi is an e-mail mailing list service that serves to provide essential safety information released by the MHLW and PMDA. Subscribing to the Medi-navi will allow you to receive this information on the day of its release.
This service is available only in Japanese.

Register here

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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.

Pharmaceuticals and Medical Devices Safety Information

No. 421 July 2025

Ministry of Health, Labour and Welfare
Pharmaceutical Safety Bureau, Japan

[Outline of Information]

No.	Subject	Measures	Outline of Information	Page
1	**Mandatory Registration of Pharmaceuticals, Medical Devices, etc. in a Product Database, and Utilization of Barcodes**		Marketing authorization holders of pharmaceuticals, medical devices, in vitro diagnostics or regenerative medical products, which are required to label barcodes (identification codes) containing information such as product codes on containers, etc. under Article 68-2-5 of the Pharmaceuticals and Medical Devices Act, are required to register product codes, etc. in a product database. In order to identify pharmaceuticals, medical devices, etc., it is necessary to check the product code against a database containing the product name. Recently, registration of product codes to a database was made mandatory. Details are presented in this section.	4
2	**Important Safety Information**	*P* *C*	Thiamazole: Regarding the revision of the PRECAUTIONS of drugs in accordance with the Notification dated June 24, 2025 , this section will present the details of important revisions as well as the case summary serving as the basis for these revisions.	8
3	**Revisions of PRECAUTIONS (No. 361)**	*P*	Desmopressin acetate hydrate (oral dosage form) (and 2 others)	11
4	**List of Products Subject to Early Post-marketing Phase Vigilance**		List of products subject to Early Post-marketing Phase Vigilance as of May 1, 2025	12

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 Minister of Health, Labour and Welfare is a duty of healthcare professionals.

If healthcare professionals such as physicians, dentists, and pharmacists detect adverse reactions, infections, or malfunctions associated with drugs, medical devices, or regenerative medical products, please report them to the Minister of Health, Labour and Welfare directly or through the marketing authorization holder. As healthcare professionals, drugstore and pharmacy personnel are also required to report adverse reactions, etc.

Please utilize the Report Reception Site for reporting.
(This service is available only in Japanese.)

https://www.pmda.go.jp/safety/reports/hcp/0002.html

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Abbreviations

ADR	Adverse Drug Reaction
BMI	Body Mass Index
EGFR	epidermal growth factor receptor
EPPV	Early Post-marketing Phase Vigilance
FPMAJ	Federation of Pharmaceutical Manufacturers' Associations of Japan
JFMDA	Japan Federation of Medical Devices Association
MAH	Marketing Authorization Holder
MHLW	Ministry of Health Labour and Welfare
PI	Package Insert
PMDA	Pharmaceuticals and Medical Devices Agency
PSB	Pharmaceutical Safety Bureau
PSD	Pharmaceutical Safety Division

1

Mandatory Registration of Pharmaceuticals, Medical Devices, etc. in a Product Database, and Utilization of Barcodes

1. Introduction

In order to prevent the occurrence or spread of health hazards due to quality defects, etc. of pharmaceuticals, medical devices, in vitro diagnostics or regenerative medical products, it is necessary to recall them promptly. To ensure this, it is important to make sure that distributors of pharmaceuticals, medical devices, in vitro diagnostics, or regenerative medical products, physicians, pharmacists, and other healthcare professionals can record and browse information, such as product names and manufacturing numbers, so that products subject to recall, etc. can be identified promptly.

In Article 68-2-5 of the Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices (Act No.145 of 1960; hereinafter referred to as the "Pharmaceuticals and Medical Devices Act"), it is made mandatory to label codes (product codes*, barcodes containing expiration dates, and manufacturing numbers or manufacturing codes) on containers, etc. to identify pharmaceuticals, medical devices, etc.

*A 14-digit code assigned to each type of packaging unit of individual pharmaceuticals, etc.

2. Mandatory registration in a product database

In order to identify pharmaceuticals, medical devices, etc., it is necessary to check the product code against a database containing the product name. Currently, based on administrative guidance (notifications), marketing authorization holders of pharmaceuticals, medical devices, etc. are required to register product codes and other information in the database. However, it has been pointed out that the registration is not always sufficient due to delays in registration, inaccurate registration details, etc., making it difficult to fully utilize the information.

Under these circumstances, the "Basic Policy for Economic and Fiscal Management and Reform 2024" (approved in a cabinet meeting on June 21, 2024) states that "the establishment of a product database for pharmaceuticals, medical devices, etc., which contributes to further improvement of medical safety and increased administrative efficiency at hospitals and other institutions, will be promoted,"* and the "Summary on revision of laws and regulations, including the Pharmaceuticals and Medical Devices Act" (the Subcommittee for Pharmaceuticals and Medical Devices Regulation of the Health Science Council of MHLW on January 10, 2025) states that "marketing authorization holders of pharmaceuticals, medical devices, in vitro diagnostics or regenerative medical products, which are required to label barcodes (identification codes) containing information such as product codes on containers, etc. under the Pharmaceuticals and Medical Devices Act, should be required to register product codes, etc. in a product database," and discussions on the establishment of a product database are currently underway.

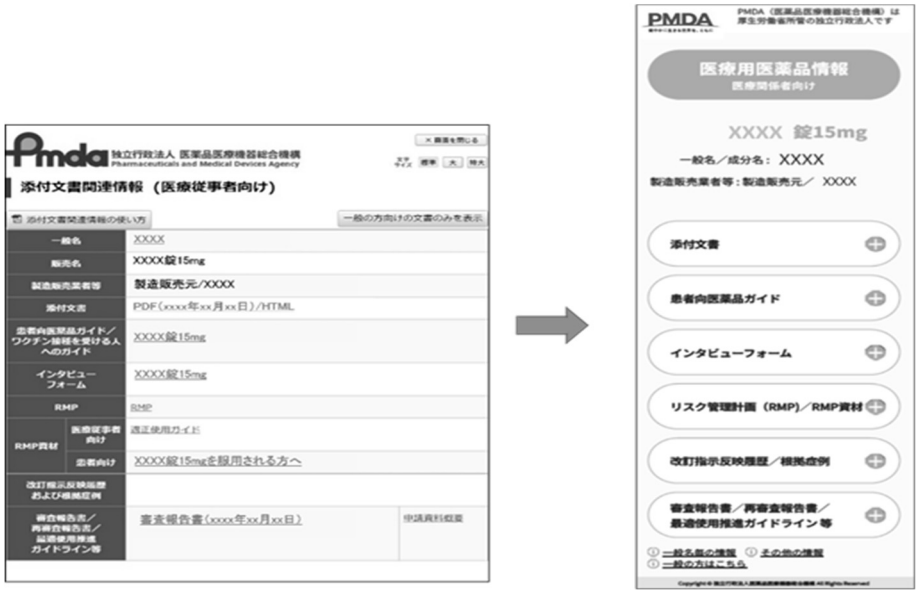
*The Basic Policy for Economic and Fiscal Management and Reform 2025 (approved in a cabinet meeting on June 13, 2025) states that "the establishment of a product database, which contributes to cyber security measures at medical institutions and the promotion of digital transformation of logistics for pharmaceuticals, medical devices, etc., will be promoted to improve medical safety".

3. Browsing package inserts, etc. utilizing barcodes

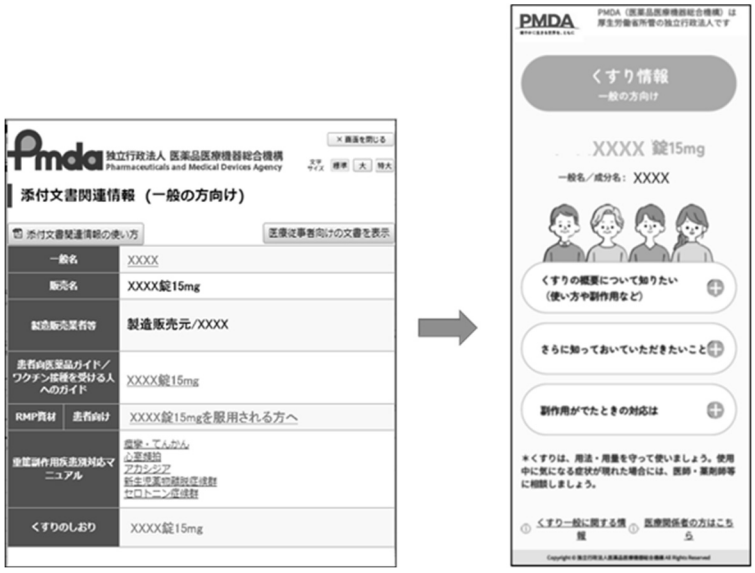
Barcodes for pharmaceuticals, etc. are utilized in various ways. For example, medical institutions, etc. can easily browse the latest information by reading the codes (GS1 codes) on the containers, etc. of pharmaceuticals, etc. with an app on a smartphone or similar device as a means of browsing electronic package inserts, etc. registered with PMDA.

One of the available apps is “PI (Package Insert)-navi,” a free app jointly developed by the Distribution System Research Institute (GS1 Japan), the Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ), and the Japan Federation of Medical Devices Association (JFMDA). In March 2025, the PMDA’s website was revamped to make the list screen of links to related documents displayed on the PI-navi and other apps more familiar to the public.

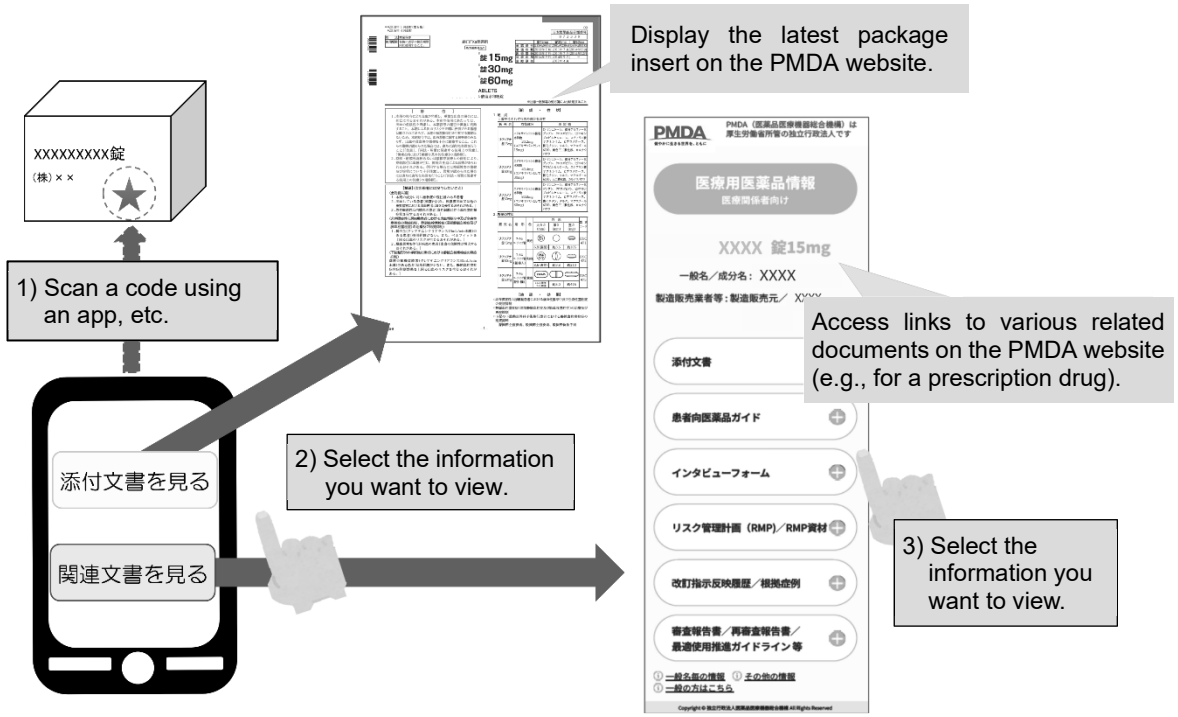
[Screen design after modification]
<Screen for healthcare professionals>
*Prescription drugs, medical devices, in vitro diagnostics, regenerative medical products



<Screen for the public>
*Prescription drugs only



[Access by GS1 barcode reading]



The PI-navi can be downloaded from the official Apple and Google stores.

iOS↵ Android↵

↵

4. Closing remark

It is expected that the use of barcodes to obtain information, such as product codes for pharmaceuticals, etc., will prevent medical accidents caused by mishandling of pharmaceuticals, etc., improve the efficiency of incoming inspection and inventory checks in the pharmacy departments at medical institutions, and ensure proper inventory in distribution at hospitals.

In addition to these efforts, the establishment of a product database and mandatory registration in the database are expected to further improve medical safety, such as ensuring traceability, and promote digital transformation of logistics. Also, it is expected that the organization of the relationship between each code, including the product code, will promote the secondary use of medical information.

5. References

- Basic Policy for Economic and Fiscal Management and Reform 2024 (Approved in a cabinet meeting on June 21, 2024)
  https://www5.cao.go.jp/keizai-shimon/kaigi/cabinet/honebuto/2024/2024_basicpolicies_ja.pdf
  (only in Japanese)

- Basic Policy for Economic and Fiscal Management and Reform 2025 (Approved in a cabinet meeting on June 13, 2025)
  https://www5.cao.go.jp/keizai-shimon/kaigi/cabinet/honebuto/2025/2025_basicpolicies_ja.pdf
  (only in Japanese)

- Summary on revision of laws and regulations, including the Pharmaceuticals and Medical Devices Act (The Subcommittee for Pharmaceuticals and Medical Devices Regulation of the Health Science Council of MHLW on January 10, 2025)
  https://www.mhlw.go.jp/content/11120000/001371285.pdf (only in Japanese)

- Change in the design of the list screen of related information displayed on the PI-navi and other apps (PSB/PSD Administrative Notice dated on April 4, 2025)
  https://www.pmda.go.jp/files/000274781.pdf (only in Japanese)

2

Important Safety Information

Regarding the revision of the PRECAUTIONS of package inserts of drugs in accordance with the Notification dated June 24, 2025, this section will present the details of important revisions as well as the case summary serving as the basis for these revisions.

1 Thiamazole

Brand name (name of company)	Mercazole Tablets 2.5 mg, 5 mg, Mercazole Injection 10 mg (Aska Pharmaceutical Co., Ltd.)
Therapeutic category	Thyroid and para-thyroid hormone preparations
Indications	Hyperthyroidism

PRECAUTIONS (Revised language is underlined.)

11. ADVERSE REACTIONS **11.1 Clinically Significant Adverse Reactions (newly added)**	Acute pancreatitis If symptoms such as upper abdominal pain, back pain, pyrexia, and vomiting or pancreatic enzyme abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.
Reference information	Number of cases (for which a causal relationship between the drug and the event is reasonably possible) collected in the PMDA's database for adverse drug reactions, etc. reports Cases involving acute pancreatitis reported in Japan: 5 (No patient mortalities) Number of patients using the drug as estimated by the MAH during the previous 1-year period: [1], [2] Approximately 240,000 [3] Approximately 3,000 Japanese market launch: [1] Tablets 2.5 mg: February 2021 [2] Tablets 5 mg: July 1956 [3] Injection 10 mg: February 1958

Case summary

No.	Patient		Daily dose/ Administration duration	Adverse reaction	
	Sex/ age	Reason for use (complication)		Clinical course and treatment	
1	Female 70s	Thyrotoxicosis Basedow's disease (hypertension, Sjogren's syndrome, osteoporosis, atrial fibrillation, cardiac failure)	15 mg 16 days	**Acute pancreatitis**	
				Day 1 of administration	Weight has been decreasing. Palpitations have been present for some time. The patient presented to the hospital for palpitations and fatigue. Cardiac failure and atrial fibrillation were identified. The patient was admitted with a diagnosis of Basedow's disease. Thiamazole and potassium iodide were initiated.
				Day 12 of administration	Pyrexia of 38.3°C, acute abdominal pain, and diarrhoea occurred. No noteworthy findings were noted other than a slightly increased CRP. Diverticulitis, which was suspected based on a plain abdominal CT scan, was not improved with cefmetazole.
				Day 16 of administration (day of discontinuation)	Acute pancreatitis was diagnosed based on increased pancreatic enzymes. Thiamazole was discontinued. The dose of potassium iodide was increased. Fluid replacement, ulinastatin, and imipenem hydrate/cilastatin sodium were initiated.
				8 days after discontinuation	Abdominal pain and pyrexia gradually improved. Imipenem hydrate/cilastatin sodium was discontinued and ulinastatin was switched to camostat mesilate. Thyroid hormones increased. Propylthiouracil was initiated, and the dose of potassium iodide was reduced. No aggravation was noted afterwards.
				16 days after discontinuation	The patient was discharged with an improved general condition.

Laboratory test value

Test item (unit)	Day 1	Day 12	Day 16 (day of discontinuation)	1 day after discontinuation	8 days after discontinuation	15 days after discontinuation	25 days after discontinuation
Amylase (IU/L)	56	76	214	336	134	195	120
Lipase (IU/L)	-	-	923	1519	269	-	214
Elastase 1 (ng/dL)	-	-	1537	3133	1703	-	1050
CRP (mg/dL)	-	0.98	9.97	13.06	0.61	0.05	0.06

Concomitant drugs: Metoprolol tartrate, olmesartan medoxomil, nifedipine, sodium risedronate hydrate, esomeprazole magnesium hydrate, mometasone furoate hydrate, bisoprolol fumarate, torasemide, apixaban, tolvaptan, digoxin, potassium iodide

Case summary

<table>
<tr><th rowspan="2">No.</th><th colspan="2">Patient</th><th rowspan="2">Daily dose/
Administration duration</th><th colspan="2">Adverse reaction</th></tr>
<tr><th>Sex/
age</th><th>Reason for use
(complication)</th><th colspan="2">Clinical course and treatment</th></tr>
<tr><td>2</td><td>Male
50s</td><td>Thyroid crisis,
Basedow's disease
(hypertension)</td><td>30 mg
2 days
↓
15 mg
1 day
↓
30 mg
4 days</td><td colspan="2">Acute pancreatitis</td></tr>
<tr><td></td><td></td><td></td><td></td><td>4 days before administration</td><td>The patient had pyrexia of 39°C. He made an emergency request and visited a nearby hospital. He returned home after being tested negative for COVID-19 and influenza.</td></tr>
<tr><td></td><td></td><td></td><td></td><td>1 day before administration</td><td>The patient visited the nearby hospital with persistent pyrexia and returned home after receiving symptomatic treatment only. Vomiting and diarrhoea were exacerbated.</td></tr>
<tr><td></td><td></td><td></td><td></td><td>Day 1 of administration</td><td>The patient visited the nearby hospital. Unrest, persistent pyrexia, tachycardia, and increased thyroid function were noted. The patient also had difficulty moving and was transferred to the reporting institution. Thiamazole was initiated after a diagnosis of thyroid crisis. Landiolol hydrochloride, hydrocortisone sodium phosphate injection, and potassium iodide were also initiated.</td></tr>
<tr><td></td><td></td><td></td><td></td><td>7 days after administration (day of discontinuation)</td><td>Epigastric pain occurred in the morning. A plain CT scan was performed, and no significant findings were noted.
Queasy and diarrhoea occurred in the afternoon. Pain spread throughout the entire abdomen.
Acetaminophen and vonoprazan fumarate were initiated for the pain.
Thiamazole was discontinued.</td></tr>
<tr><td></td><td></td><td></td><td></td><td>1 day after discontinuation</td><td>The symptoms did not improve. A contrast-enhanced CT was performed. Increased adipose tissue concentration around the pancreas was noted. Amylase and P-amylase were increased. Acute pancreatitis was diagnosed. Association of the pancreatitis with cholelithiasis, alcohol consumption, or IgG4 was denied. Drug-induced pancreatitis was suggested.
Fasting and fluid replacement were initiated.</td></tr>
<tr><td></td><td></td><td></td><td></td><td>3 days after discontinuation</td><td>The patient recovered from acute pancreatitis.</td></tr>
<tr><td></td><td colspan="5">Laboratory test value
<table>
<tr><th>Test item (unit)</th><th>Day 1 of administration</th><th>1 day after discontinuation</th><th>3 days after discontinuation</th><th>4 days after discontinuation</th><th>5 days after discontinuation</th></tr>
<tr><td>Amylase (U/L)</td><td>30</td><td>155</td><td>46</td><td>25</td><td>39</td></tr>
<tr><td>P-amylase (U/L)</td><td>-</td><td>136</td><td>35</td><td>16</td><td>22</td></tr>
<tr><td>Lipase (U/L)</td><td>-</td><td>182</td><td>-</td><td>-</td><td>26</td></tr>
</table></td></tr>
<tr><td></td><td colspan="5">Concomitant drugs: Landiolol hydrochloride, hydrocortisone sodium phosphate, potassium iodide</td></tr>
</table>

3

Revisions of PRECAUTIONS (No. 361)

This section presents details of revisions to the PRECAUTIONS and brand names of drugs that have been revised in accordance with the Notification dated June 24, 2025.

1 Pituitary hormone preparations
Desmopressin acetate hydrate (oral dosage form)

Brand name	Minirinmelt OD Tablets 25 μg, 50 μg, 60 μg, 120 μg, 240 μg (Ferring Pharmaceuticals Co., Ltd.)
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (newly added)	Anaphylaxis

2 Pituitary hormone preparations
Desmopressin acetate hydrate (nasal preparations)

Brand name	Desmopressin Nasal Spray 2.5 μg “Ferring” (Ferring Pharmaceuticals Co., Ltd.), Desmopressin Spray 10 Kyowa, and the others (Ferring Pharmaceuticals Co., Ltd. and the others)
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complication or History of Diseases, etc.	Patients with a history of hypersensitivity to any of the ingredients contained in this drug This drug should not be administered except in cases where such use is considered absolutely necessary for the treatment. Anaphylaxis may occur.
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (newly added)	Anaphylaxis

3 Thyroid and para-thyroid hormone preparations
Thiamazole

Brand name	Mercazole Tablets 2.5 mg, 5 mg, Mercazole Injection 10 mg (Aska Pharmaceutical Co., Ltd.)
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (newly added)	Acute pancreatitis If symptoms such as upper abdominal pain, back pain, pyrexia, and vomiting or pancreatic enzyme abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.

4

List of Products Subject to Early Post-marketing Phase Vigilance

Early Post-marketing Phase Vigilance (EPPV) was established in 2001. This unique system for newly-approved drug products refers to any safety assurance activities that are conducted within a period of 6 months just after marketing of a new drug. The MAH responsible for a new drug in the EPPV period is required to collect adverse drug reactions (ADRs) data from all medical institutions where the drug is used and to take safety measures as appropriate. The aim of EPPV is to promote the rational and appropriate use of drugs in medical treatments and to facilitate prompt action for the prevention of serious ADRs. EPPV is specified as a condition of product approval.

(As of May 31, 2025)
◎: Products for which EPPV was initiated after May 1, 2025

	Nonproprietary name Brand name	Name of the MAH	Date of EPPV initiation
◎	Amivantamab (genetical recombination)[*1] Rybrevant Intravenous Infusion 350 mg	Janssen Pharmaceutical K.K.	May 21, 2025
◎	Tisotumab vedotin (genetical recombination) Tivdak for Intravenous Infusion 40 mg	Genmab K.K.	May 21, 2025
◎	Lazertinib mesilate hydrate Lazcluze Tablets 80 mg, 240 mg	Janssen Pharmaceutical K.K.	May 21, 2025
◎	Guselkumab (genetical recombination)[*2] Tremfya Intravenous Infusion 200 mg, Tremfya Subcutaneous Injection 200 mg Syringe, 200 mg Pen, 100 mg Syringe	Janssen Pharmaceutical K.K.	May 21, 2025
◎	Mavacamten Camzyos capsules 5 mg, 2.5 mg, 1 mg	Bristol-Myers Squibb K.K.	May 21, 2025
◎	Acoramidis hydrochloride Beyonttra tablets 400 mg	Alexion Pharma Godo Kaisha	May 21, 2025
◎	Amivantamab (genetical recombination)[*3] Rybrevant Intravenous Infusion 350 mg	Janssen Pharmaceutical K.K.	May 19, 2025
◎	Iptacopan hydrochloride hydrate[*4] Fabhalta capsules 200 mg	Novartis Pharma K.K.	May 19, 2025
	Atropine sulfate hydrate[*5] Ryjusea Mini ophthalmic solution 0.025%	Santen Pharmaceutical Co., Ltd.	April 21, 2025
	Garadacimab (genetical recombination) Andembry S.C. Injection 200 mg Pens	CSL Behring K.K.	April 18, 2025
	Brivaracetam Briviact for I.V. injection 25 mg	UCB Japan Co. Ltd.	April 17, 2025
	Tarlatamab (genetical recombination) Imdelltra For I.V. Infusion 1 mg, 10 mg	Amgen K.K.	April 16, 2025
	Tirzepatide[*6] Zepbound Subcutaneous Injection Ateos 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15	Eli Lilly Japan K.K.	April 11,2025

Nonproprietary name Brand name	Name of the MAH	Date of EPPV initiation
mg		
Benralizumab (genetical recombination)[*7] Fasenra Subcutaneous Injection 30 mg Pen	AstraZeneca K.K.	April 1, 2025
Letermovir[*8] Prevymis Tablets 240 mg, Prevymis Intravenous Infusion 240 mg	MSD K.K.	March 27, 2025
Marstacimab (genetical recombination) Hympavzi S.C. Injection 150 mg Pen	Pfizer Japan Inc.	March 24, 2025
Teclistamab (genetical recombination) Tecvayli Subcutaneous Injection 153 mg, 30 mg	Janssen Pharmaceutical K.K.	March 19, 2025
Mosunetuzumab (genetical recombination) Lunsumio for Intravenous Infusion 1 mg, 30 mg	Chugai Pharmaceutical Co., Ltd.	March19, 2025
Datopotamab deruxtecan (genetical recombination) Datroway for Intravenous Drip Infusion 100 mg	Daiichi Sankyo Co., Ltd.	March 19, 2025
Selexipag Uptravi Tablets for Pediatric 0.05 mg	Nippon Shinyaku Co., Ltd.	March 19, 2025
Ozanimod hydrochloride Zeposia capsules 0.92 mg, Zeposia capsules starter pack	Bristol-Myers Squibb K.K.	March 19, 2025
Tofersen Qalsody Intrathecal injection 100 mg	Biogen Japan Ltd	March 19, 2025
Zanubrutinib Brukinsa capsules 80 mg	BeiGene Japan GK	March 19, 2025
Patiromer sorbitex calcium Veltassa 8.4 g powder for suspension (single-dose package)	Zeria Pharmaceutical Co., Ltd.	March 17, 2025
Flortaucipir (^{18}F) Tauvid Injection	PDRadiopharma Inc.	March 3, 2025
Insulin Icodec (genetical recombination) Awiqli injection FlexTouch 300 units, 700 units	Novo Nordisk Pharma Ltd.	January 30, 2025
Articaine hydrochloride/adrenaline bitartrate Septocaine Combination Injection Cartridge	GC SHOWAYAKUHIN CORPORATION	January 21, 2025
Amifampridine phosphate Firdapse Tablets 10 mg	DyDo Pharma, Inc.	January 15, 2025
Benralizumab (genetical recombination)[*9] Fasenra Subcutaneous Injection 30 mg Syringe	AstraZeneca K.K.	December 27, 2024
Efgartigimod alfa (genetical recombination)/vorhyaluronidase alfa (genetical recombination)[*10] Vyvdura Combination Subcutaneous	argenx Japan K.K.	December 27, 2024

	Nonproprietary name Brand name	Name of the MAH	Date of EPPV initiation
	Injection		
	Daridorexant hydrochloride Quviviq Tablets 25 mg, 50 mg	Nxera Pharma Japan Co., Ltd.	December 19, 2024
	Aceneuramic acid Acenobel Extended Release Tablets 500 mg	Nobelpharma Co., Ltd.	December 19, 2024
	Estetrol hydrate/drospirenone alyssa combination tablets	Fuji Pharma Co., Ltd.	December 3, 2024

*1 Coadministration with lazertinib mesilate hydrate for unresectable, advanced or recurrent *EGFR* mutation-positive non-small cell lung cancer

*2 Maintenance therapy for moderate to severe ulcerative colitis (only in patients who have had an inadequate response to conventional treatments)

*3 Coadministration with carboplatin and pemetrexed sodium hydrate for unresectable, advanced or recurrent *EGFR* mutation-positive non-small cell lung cancer

*4 C3 nephropathy

*5 Slowing the progression of myopia

*6 Treatment of obesity
The use is limited to patients with either hypertension, dyslipidaemia, or type 2 diabetes mellitus who have not sufficiently responded to treatment with dietary and exercise therapy and who fall under the following conditions:
* BMI of 27 kg/m^2 or greater in the presence of at least two obesity-related comorbidities
* BMI of 35 kg/m^2 or greater

*7 Eosinophilic granulomatosis with polyangiitis in patients who have not sufficiently responded to conventional treatments

*8 Addition of a pediatric dosage for the indication below:
Prophylaxis of cytomegalovirus disease for the following:
* Allogeneic haematopoietic stem cell transplantation
* Organ transplantation

*9 Eosinophilic granulomatosis with polyangiitis in patients who have not sufficiently responded to conventional treatments

*10 Chronic inflammatory demyelinating polyradiculoneuritis