API demand in Japan, FY2025–FY2027: key points

This document is a sample. The substance (Substance X), all companies and all market figures are fictional and do not relate to any actual product. The structure, tables, charts and method are those of the report we prepare for a specific substance. The backtest results on page 6 are the actual results of our model.

This report estimates demand in Japan for the active pharmaceutical ingredient (API) Substance X hydrochloride. Substance X is sold as single-ingredient tablets (5 mg, 10 mg) and as a fixed-dose combination tablet. Generics of the combination were listed on the National Health Insurance (NHI) price list in December 2025, so API demand for the combination is now moving from the originator to the generic companies. **How fast it moves** is the main difference between the three scenarios.

Total API demand, FY2027

5,387 kg

Scenario B; −1.9% against the FY2024 actual of 5,491 kg. Scenarios A–C: 4,737–5,941 kg.

Generic-side demand, FY2027

3,917 kg

Scenario B; FY2024 actual: 3,128 kg. Scenarios A–C: 3,203–4,608 kg.

Buyers and registered API sources

11 MAHs · 7 MFs

1 originator and 10 generic marketing authorisation holders (MAHs); 7 Master File (MF) registrations (India 4, Japan 1, Italy 1, China 1).

Table 1. API demand by scenario (kg per year, as Substance X hydrochloride; prescription-based)

Scenario	Assumption	Total FY2026	Total FY2027	Generic side FY2027	Generic side, % of total	Generic side: combination
Scenario A	Volume at the lower bound; switching to generics follows the slowest precedents	5,042	4,737	3,203	67.6%	580
Scenario B	Central volume forecast; switching follows the median of precedents	5,434	5,387	3,917	72.7%	911
Scenario C	Volume at the upper bound; switching follows the fastest precedents	5,767	5,941	4,608	77.6%	1,267

Basis of the figures

- **Actual to FY2024:** prescribed quantities by product in NDB Open Data (statistics from the National Database of health insurance claims, published by the Ministry of Health, Labour and Welfare, MHLW), multiplied by the labelled amount of Substance X per tablet.
- **FY2025 estimate:** annualised from the monthly NDB release (April–June 2025): 5,465 kg (−0.5% vs FY2024).
- **FY2026–FY2027 forecast:** our forecasting model. The range A–C is set from the past forecast errors of the same model (page 6).
- Fiscal years run from April to March. Price revisions and regulatory changes after 24 November 2026 are not included.

What determines the scenario

- **Generic share of the combination** in the next monthly NDB releases. For January–March 2026 the scenarios assume 13% (A), 20% (B) and 28% (C); thresholds are on page 3.
- **Supply status** of the generic products: 3 of 22 generic products are under limited shipment (page 5).
- **New generic listings** (June and December) and **new MF registrations** for Substance X on the list of the Pharmaceuticals and Medical Devices Agency (PMDA).

Implications for supply planning

The quantity most likely to be open to a change of API source is the generic side: 3,917 kg in FY2027 under Scenario B, of which 911 kg is new to the generic side through the combination generics. One combination generic uses the same excipients as the originator product and may share its API source (page 4). Manufacturing requirement including yield and process loss (assumed 5–15%): 5,656–6,195 kg for the total under Scenario B.

All quantities are based on prescriptions reimbursed by health insurance. Inventories held by manufacturers and wholesalers, exports and development batches are not included. Figures for FY2025 onwards are estimates and forecasts by Healthle and are not guaranteed.

Source: Ministry of Health, Labour and Welfare (MHLW), NDB Open Data (annual and monthly releases); PMDA, package inserts and list of MF registrations; estimates and forecasts by Healthle.

API demand in kilograms: actual, estimate and forecast

Total API demand was 5,491 kg in FY2024. The single-ingredient tablets are declining by 1–3% a year, while the combination tablet has grown every year since FY2019. For FY2027 the central forecast is 5,387 kg, with a range of 4,737–5,941 kg.

Figure 1. API demand for Substance X hydrochloride (kg per year, all product groups)

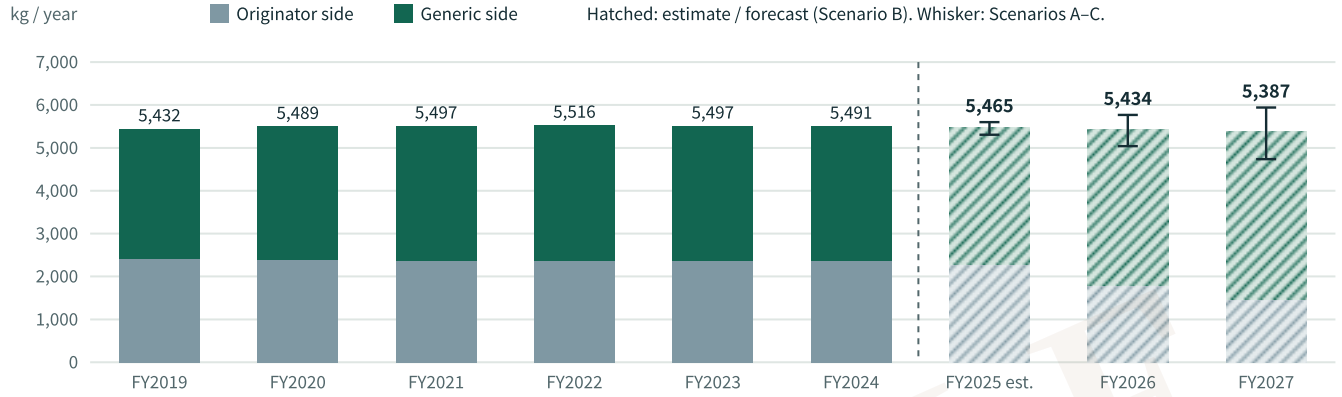


Table 2. API demand by product group (kg per year). Forecast years show Scenario B, with Scenarios A–C below.

Product group	FY2022 actual	FY2023 actual	FY2024 actual	FY2025 estimate	FY2026 forecast	FY2027 forecast
Single-ingredient tablets 5 mg	1,640	1,592	1,554	1,510 1,467–1,546	1,472 1,368–1,559	1,431 1,262–1,573
Single-ingredient tablets 10 mg	2,396	2,348	2,313	2,281 2,216–2,332	2,244 2,089–2,373	2,204 1,948–2,419
Combination tablets (X 10 mg)	1,480	1,557	1,624	1,674 1,621–1,721	1,718 1,585–1,835	1,752 1,527–1,949
Total	**5,516**	**5,497**	**5,491**	**5,465** **5,304–5,599**	**5,434** **5,042–5,767**	**5,387** **4,737–5,941**
of which generic side	3,152	3,136	3,128	3,190 3,056–3,317	3,639 3,197–4,086	3,917 3,203–4,608
of which originator side	2,364	2,361	2,363	2,275 2,248–2,282	1,795 1,681–1,845	1,470 1,333–1,534
Manufacturing requirement (total)	5,792–6,343	5,772–6,322	5,766–6,315	6,012 5,569–6,439	5,977 5,294–6,632	5,926 4,974–6,832

API quantity = prescribed quantity of each product × labelled amount per tablet, expressed as the hydrochloride. The manufacturing requirement multiplies the API quantity by 1.05–1.15 for yield and process loss in oral solid dosage forms; this factor is an assumption. Actual years show the range only.

Table 3. Latest monthly actuals (NDB monthly release; million tablets)

Month	Single-ingredient tablets	Year on year	Generic share	Combination tablets	Year on year	API (kg)
April 2025	44.97	−2.5%	81.3%	14.31	+3.6%	464
May 2025	43.16	−3.2%	81.5%	13.72	+2.7%	445
June 2025	44.49	−1.9%	81.8%	14.01	+3.1%	457
April–June 2025	**132.62**			**42.04**		**1,366**

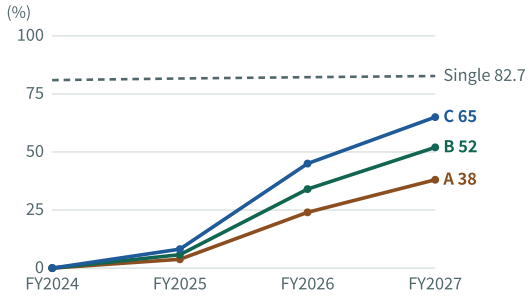
The monthly release covers April–June 2025. Claims for May and June that arrive late are not yet included in the release; the FY2025 estimate corrects for this. Combination generics were listed in December 2025 and do not yet appear in the monthly data; their FY2025 quantity is a scenario assumption.

Source: MHLW, NDB Open Data (annual releases to FY2024; monthly release for April–June 2025), processed by Healthle. Labelled amounts from PMDA package inserts. Estimates and forecasts by Healthle.

Three scenarios and the shift to generics

For the single-ingredient tablets, generics already accounted for 80.9% of the quantity in FY2024 and the share changes little. For the combination tablet, generics were first listed in December 2025 (6 companies). The scenarios differ mainly in how quickly prescriptions of the combination move to generics.

Figure 2. Generic share, combination (%)



Share of quantity, by scenario. Dashed line: generic share of the single-ingredient tablets (Scenario B).

How the scenarios are set

- **Scenario A** — the generic share of the combination reaches 38% in FY2027, the slowest of the precedents; volume at the lower bound of the forecast range.
- **Scenario B** — 52% in FY2027, the median of the precedents; central volume forecast.
- **Scenario C** — 65% in FY2027, the fastest of the precedents; volume at the upper bound.
- Precedents are past generic entries in the same therapeutic area, measured by year since listing. The volume range is about an 80% interval based on past forecast errors (page 6); Substance X is a stable, mature product, so its range is narrower than for most substances.
- In the first year after listing, generic companies build up distribution stock, so their API purchases may exceed the prescription-based quantity. This is not included in the table.

Table 4. Generic share of the combination and API demand by side (kg per year)

	Generic share of the combination			FY2026 (kg)			FY2027 (kg)		
Scenario	FY2025	FY2026	FY2027	Generic: single	Generic: comb.	Originator	Generic: single	Generic: comb.	Originator
Scenario A	3.8%	24.0%	38.0%	2,817	380	1,845	2,623	580	1,534
Scenario B	5.8%	34.0%	52.0%	3,055	584	1,795	3,006	911	1,470
Scenario C	8.2%	45.0%	65.0%	3,260	826	1,681	3,341	1,267	1,333

Table 5. Monitoring indicators and thresholds for switching scenario

Indicator	Threshold	Where and when
Generic share of the combination, January–March 2026 (monthly NDB data)	Scenarios assume A 13%, B 20%, C 28% Above 24% → C; below 16.5% → A	MHLW monthly NDB release. Publication dates are not announced in advance.
Generic share of the combination, April–June 2026 (monthly NDB data)	Scenarios assume A 19%, B 28%, C 38% Above 33% → C; below 23.5% → A	
Supply status of generic products (limited shipment or suspension)	A rise in the share under limited shipment slows switching (towards A)	MHLW supply-status list, updated several times a month. Currently 11.8% of generic quantity.
New generic listings and MF registrations for Substance X	Additional entrants raise the generic side (towards C) and divide it among more buyers	National Health Insurance (NHI) price listing in June and December; PMDA list of MF registrations.
Dispensing volume of the therapeutic class	Used to check the total volume, not to switch scenario	MHLW monthly dispensing statistics, published about 4–5 months after the month.

Source: MHLW, NDB Open Data, supply-status list of prescription drugs, and NHI price list, processed by Healthle. Scenario settings and forecasts by Healthle.

API demand by marketing authorisation holder

The API quantity is divided among the marketing authorisation holders (MAHs) that sell the finished products. In FY2027 under Scenario B, the three largest generic MAHs (Generic A, Generic B, Generic C) account for 65% of the generic side.

Table 6. API demand by marketing authorisation holder (kg per year, as Substance X hydrochloride)

MAH	Type	Products	FY2024 actual	FY2025 estimate	FY2027 Scenario B	FY2027 indicative range	Share of generic side	Note
Originator Co.	Originator	Single + Comb.	2,363	2,275	**1,470**	1,333–1,534	–	
Generic A	Generic	Single + Comb.	857	891	**1,103**	673–1,512	28.2%	Comb. listed Dec 2025
Generic B	Generic	Single + Comb.	682	680	**783**	506–1,054	20.0%	Comb. listed Dec 2025
Generic C	Generic	Single + Comb.	507	532	**672**	403–927	17.2%	Comb. listed Dec 2025
Generic D	Generic	Single	360	346	**337**	250–430	8.6%	
Generic E	Generic	Single	278	272	**265**	196–338	6.8%	
Generic F	Generic	Single + Comb.	197	204	**247**	153–337	6.3%	Comb. listed Dec 2025
Generic J	Generic	Comb.	0	20	**191**	37–319	4.9%	Comb. listed Dec 2025 same excipients as originator
Generic G	Generic	Single	144	139	**135**	100–172	3.4%	
Generic H	Generic	Single	103	96	**93**	69–120	2.4%	
Generic K	Generic	Comb.	0	10	**91**	17–152	2.3%	Comb. listed Dec 2025
Generic side, total			**3,128**	**3,190**	**3,917**	**3,203–4,608**	**100%**	**Same as Table 2**
Total			**5,491**	**5,465**	**5,387**	**4,737–5,941**		**Same as Table 2**

FY2024: actual prescribed quantity of each company's products. FY2025: each company's share in the monthly release (April–June 2025) applied to the FY2025 estimate; combination generics, which are not yet in the monthly data, are assigned by the allocation method below. Single-ingredient tablets in FY2027 keep the latest shares. The indicative range combines Scenarios A–C with the past variation of company shares.

Newly listed combination generics

- No actual data exist yet for the combination generics listed in December 2025. Their quantities are assigned from each company's record in past generic entries, whether the excipients match the originator product, and the timing of listing.
- In a leave-one-substance-out test on past generic entries, the assigned company shares were off by 6.9 percentage points on average in the second fiscal year after listing (FY2027 here), against 8.8 for an equal split (page 6). Individual company figures are a guide to rank and scale and will be replaced by actual data when published.

Reading the table

- Where a generic uses the same excipients as the originator product, its share in past entries has tended to be large, and its API may come from the same source as the originator. The quantity open to other sources is then smaller than the generic-side total: 3,726 kg instead of 3,917 kg in FY2027 (Scenario B).
- Figures are prescription-based. Contract manufacturing relationships and API purchasing are shown on page 5 where they are publicly disclosed; API suppliers of individual products are not public.

Source: MHLW, NDB Open Data (annual and monthly releases) and NHI price list; PMDA package inserts (excipients). Allocation and forecasts by Healthle.

MF registrations, manufacturing and supply status

The list published by the Pharmaceuticals and Medical Devices Agency (PMDA) shows 7 MF registrations for Substance X (India 4, Japan 1, Italy 1, China 1). Of the 10 generic MAHs, 8 publish manufacturing information that we could access: 7 disclose India as a country of API manufacture and 4 report more than one API source.

Table 7. MF registrations for Substance X (PMDA list)

Registrant	Country	First registered	Latest change
Registrant 1	Japan	Mar 2009	Jun 2021
Registrant 2	Italy	Aug 2011	Feb 2019
Registrant 3	India	Nov 2015	Apr 2023
Registrant 4	India	May 2016	Sep 2022
Registrant 5	China	Jul 2019	Jul 2019
Registrant 6	India	Oct 2023	Oct 2023
Registrant 7	India	Feb 2025	Feb 2025

The actual report gives registrant names, MF numbers and in-country caretakers as published. An MF registration shows that a file is registered; it does not show which products use that API.

Supply status of generic products

- In the MHLW list of 16 November 2026, 3 of 22 generic products of Substance X are under limited shipment and 0 are suspended. They account for 11.8% of generic quantity (FY2024 basis).
- The actual report lists each product under limited shipment with the reason stated by the company and the date of the last update, and tracks the share over time.

Manufacturing by company

- Three generic MAHs have their tablets manufactured by another MAH in Table 8. Grouped by the company that manufactures the tablets, the generic side is concentrated in fewer manufacturers than the number of MAHs suggests.
- The Excel workbook includes the quantities of Table 6 regrouped by manufacturing company.

Table 8. Manufacturing information disclosed by generic MAHs (company disclosures under the MHLW stable-supply guideline, “Form 1”)

MAH	Tablet manufacturer	Country of API manufacture	More than one API source	Disclosure
Generic A	In-house	India; Japan	Yes	Accessed
Generic B	In-house	India	No	Accessed
Generic C	Contract: Generic A	India; Japan	Yes	Accessed
Generic D	In-house	Italy; India	Yes	Accessed
Generic E	Contract: Generic D	Italy; India	Yes	Accessed
Generic F	In-house	China	No	Accessed
Generic G	Not confirmed	–	–	Disclosure not accessible
Generic H	Contract: Generic B	India	No	Accessed
Generic J	Not confirmed	–	–	Disclosure not accessible
Generic K	In-house	India	No	Accessed

Generic MAHs in Japan publish, product by product, the type of manufacturing (in-house or contract), the finished-product manufacturer, the countries of API manufacture and whether the API is purchased from more than one source. The name of the API supplier is not part of the disclosure. Some companies restrict access to healthcare professionals or registered users; these are shown as “Disclosure not accessible”.

What this page adds to the demand figures

The kilogram figures show how much API the market needs. This page shows who holds registrations to supply it, which MAHs already buy from more than one country, and where the tablets are actually made. Read together with Table 6, it indicates which buyers account for most of the generic-side quantity and how they currently source.

Source: PMDA, list of MF registrations; MHLW, supply-status list of prescription drugs; company disclosures (Form 1) on each MAH's website, compiled by Healthle.

How far past forecasts differed from observed data

The figures on this page are actual results of our forecasting model, not fictional sample data.

We refitted the model at past dates, using prescription data only up to each date, and compared its forecasts with what was later observed. Across substances with an annual value of JPY 1 billion or more at NHI prices, the median error was 6.7% for the current fiscal year and 10.1% for the following year.

Table 9. Backtest of volume forecasts by substance (median absolute error)

Method	Current fiscal year (FY2026 in this report)	Following fiscal year (FY2027 in this report)
Assume no change from the previous year	10.0%	14.1%
Population structure and trend formula	8.5%	11.3%
Method used in this report (recent growth by substance + machine learning)	**6.7%**	**10.1%**

Error = |forecast ÷ actual − 1|. About 710–760 substances with an annual value of JPY 1 billion or more at NHI prices. Current fiscal year: average of four forecast origins (FY2019–FY2022); following fiscal year: three origins (FY2019–FY2021). Volume is aggregated by substance at constant prices. The tested version starts from annual data; the effect of adding the monthly release as the starting point has not yet been measured against actuals.

Table 10. Other checks

Item	Result
FY2025 estimate from monthly data (April–June annualised)	Applying the same method to FY2024 gave a median error of 1.2% (691 substances with an annual value of JPY 1 billion or more) and 1.6% (1,395 substances with JPY 100 million or more). This could be tested for one year only.
Forecast range (A–C)	In the backtest, the 80% range contained the actual value in 80–88% of cases.
Generic share	Set from switching curves by year since generic entry. One year after the latest actual year, the share was off by 4–6 percentage points on average in three tests (7–8 points within three years of entry). Two and three years ahead, in one test: 6.8 and 9.4 points.
Allocation to companies after generic entry	Leave-one-substance-out test on substances first listed between April 2019 and March 2024 with three or more generic entrants (value-based shares). Fiscal year after listing (38 substances, 334 company entries): assigned shares were off by 7.3 percentage points on average, against 10.2 for an equal split; the largest company was identified in 50% of substances. Second year (24 substances, 238 entries): 6.9 against 8.8 points.

Limits of the method

- The accuracy rests mainly on each substance's own recent growth. Information on price revisions, generic listings and approvals is included in the model, but added little to accuracy in the backtest.
- For the following fiscal year, the method was less accurate than the population and trend formula in one of the three forecast origins tested (the origin affected by COVID-19). Sudden changes such as supply shortages and regulatory changes are not forecast.
- Company-level figures after a new generic entry are the least certain part of the report. For companies with a share of 5% or more, the median error of the assigned share was about 40% of the share itself in the fiscal year after listing and about 34% in the second year (equal split: about 54% and 44%).
- The forecast is not built up from patient numbers by disease. Quantities are prescription-based and do not reflect inventories or purchasing contracts.

Source: Tests by Healthle using MHLW NDB Open Data (FY2014–FY2024 annual releases and the monthly release for April–June 2025), the NHI price list and PMDA package inserts.

Method, sources and how to order

The report is produced from an item-level database that links Japan's public data on prescription drugs, with a demand estimation and forecasting model on top of it.

1. Linked public data
Prescribed quantities (NDB Open Data, annual and monthly), NHI price list, package inserts, supply status, MF registrations and company disclosures, linked product by product.

→

2. Demand model
Volume by substance from recent growth and a machine-learning model; generic share from switching curves; allocation to companies from past entries.

→

3. Kilograms and scenarios
Conversion to API kilograms by strength, three scenarios, monitoring indicators, and disclosure of past forecast errors.

API demand (kg) = Σ over products [prescribed quantity × labelled amount of the substance per unit]
Company figure = product-group quantity × company share | Manufacturing requirement = API demand × yield factor

Period	How the figure is obtained
Actual (to FY2024)	NDB Open Data annual releases: prescribed quantity by product, converted with the labelled amount in the package insert.
Estimate (FY2025)	Monthly NDB release (April–June 2025) annualised, with correction for late claims and seasonality of the therapeutic class.
Forecast (FY2026–FY2027)	Forecasting model; Scenarios A–C from past forecast errors and precedents of generic switching. The Excel workbook adds an indicative extension to FY2030.

Source	Publisher	Use
NDB Open Data (annual; monthly release)	MHLW	Prescribed quantity by product, originator and generic, by company
NHI price list; package inserts	MHLW; PMDA	Products, strengths, MAHs, labelled amount per unit, excipients
Supply-status list of prescription drugs	MHLW	Limited shipment and suspension by product
List of MF registrations	PMDA	Registrants, countries and dates of registration
Company disclosures under the stable-supply guideline (Form 1)	Each MAH	Finished-product manufacturer, countries of API manufacture, multiple sourcing
Monthly dispensing statistics	MHLW	Recent volume of the therapeutic class; seasonality

Deliverables and how to order

1. **Tell us the substance** (for example, by MF registration number). One report covers one substance, including all dosage forms and combinations that contain it.
2. **We confirm coverage.** We check that the public data resolve the substance at product level and tell you what the report can and cannot show before you order.
3. **We deliver** the PDF report in the structure of this sample and an Excel workbook: kilograms by year, product group and scenario; figures by MAH and by manufacturing company; monthly actuals; MF registrations; disclosed manufacturing information; sources.

Price JPY 198,000 per substance (excluding tax). **Language** English or Japanese.
Contact Healthle, Inc. www.healthle.jp/en#request

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Source: Publishers as shown in the table above. The actual report lists the URL and access date of each source.