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There is a large room for rewarding innovation

"Joint Drug Market Simulation by EFPIA/QuintilesIMS"

May 31, 2017

EFPIA-J PEC

Kuniyuki HARA

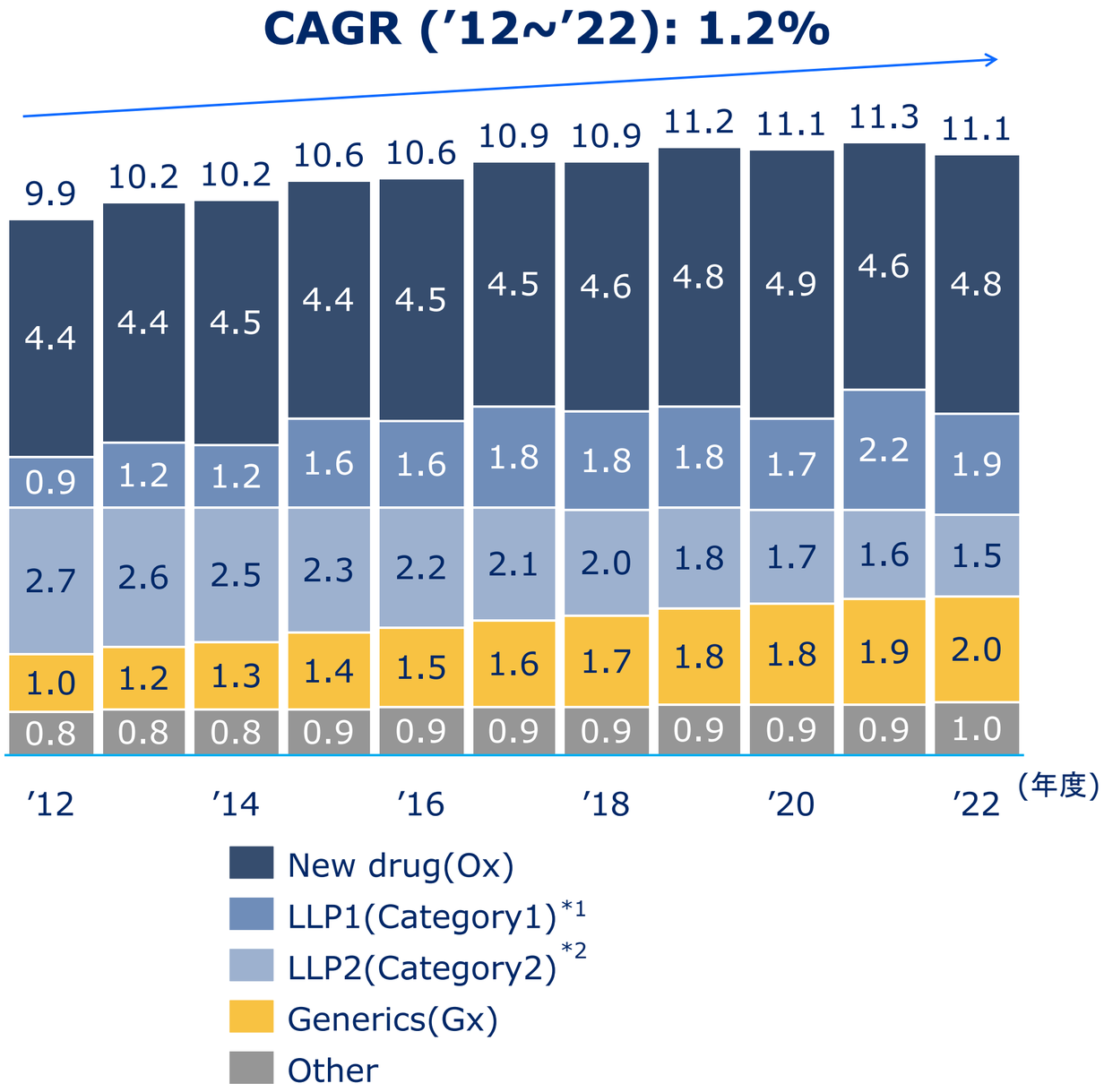
Introduction

A study into mid-long term ethical drug expenditures

Goal:

- Necessity of decision making for allocation of budget and the reform of drug pricing system based on precise information.
- EFPIA has conducted a study which modeled the mid-long term ethical drug market in collaboration with QuintilesIMS based on the updated pricing system as well as the recent trend of pharmaceutical environment from 2012.
- EFPIA conducted again the long term simulation till 2026 for the discussion on fundamental drug pricing system reform.

At 2012 project, EFPIA made forecast till 2022



*1 LLP whose Gx has been launched by Mar. 2010(Prior to 2009)
*2 LLP whose GX launched after Apr. 2010 but before 2022

Main topics	Assumption
1 **Further promotion of generic and its penetration**	Set penetration peak to 40-80% *(Actual for past 2 years:33- 66%, 120% up expected)*
2 **Policy change in additional cut to LLP**	0% additional reduction for each NHI price revision
3 **Expansion of special price reduction**	5% special cut at first NHI price revision after first generic launch
4 **Expansion of re-pricing for market expansion**	0.37% market shrink assumed for every price revision
5 **Number of newly launched medicinal entities**	Set average to 40 *(10% increase from actual of past 2 years)*
6 **Sales forecast of newly launched medicinal entities**	Set peak quarterly sales to 2.5 Bio yen (10 Bio yen /year)

Source: EFPIA-IMS Project "Making Innovation Premium Permanent" (2012)

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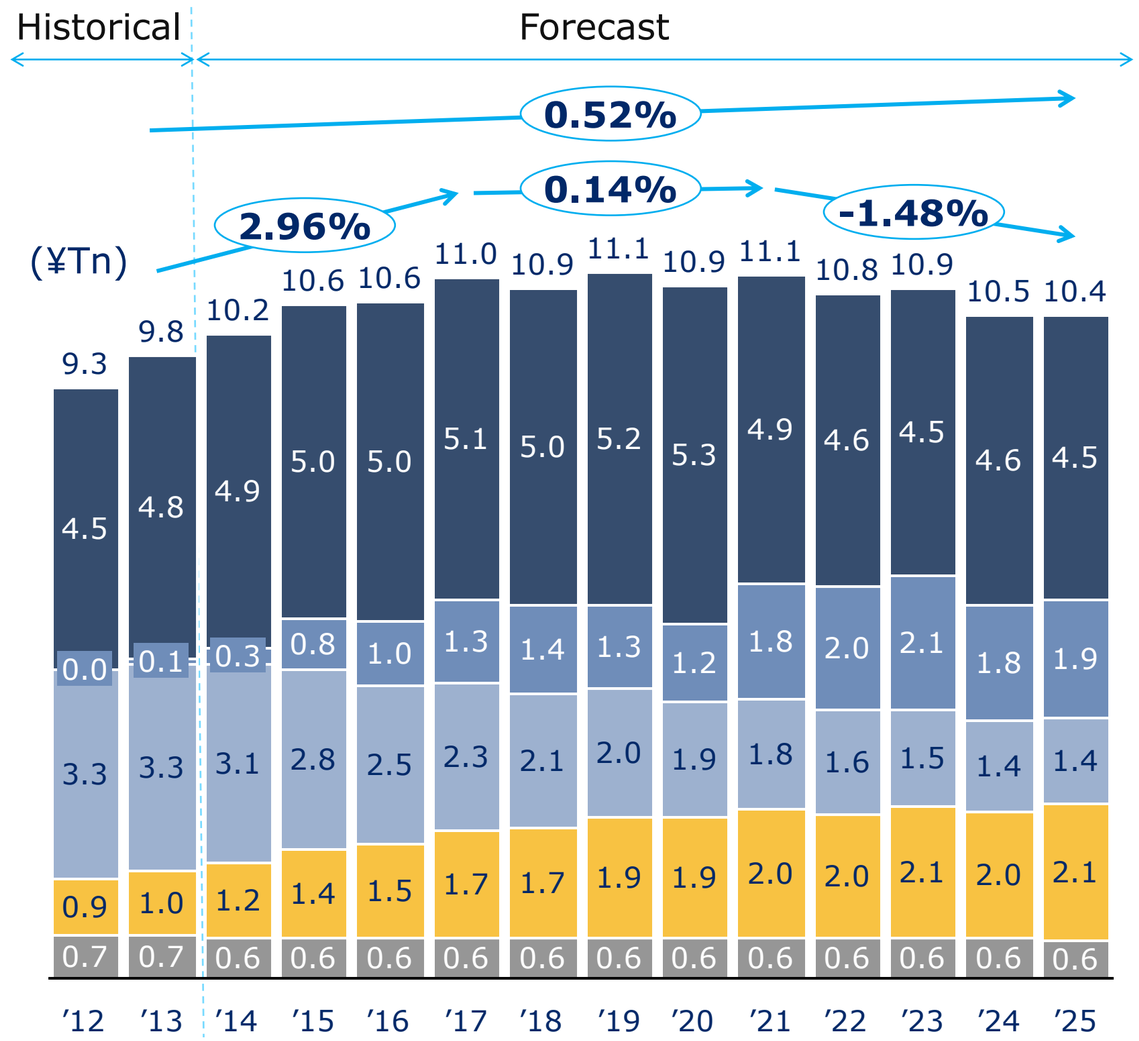
At 2014 Project,

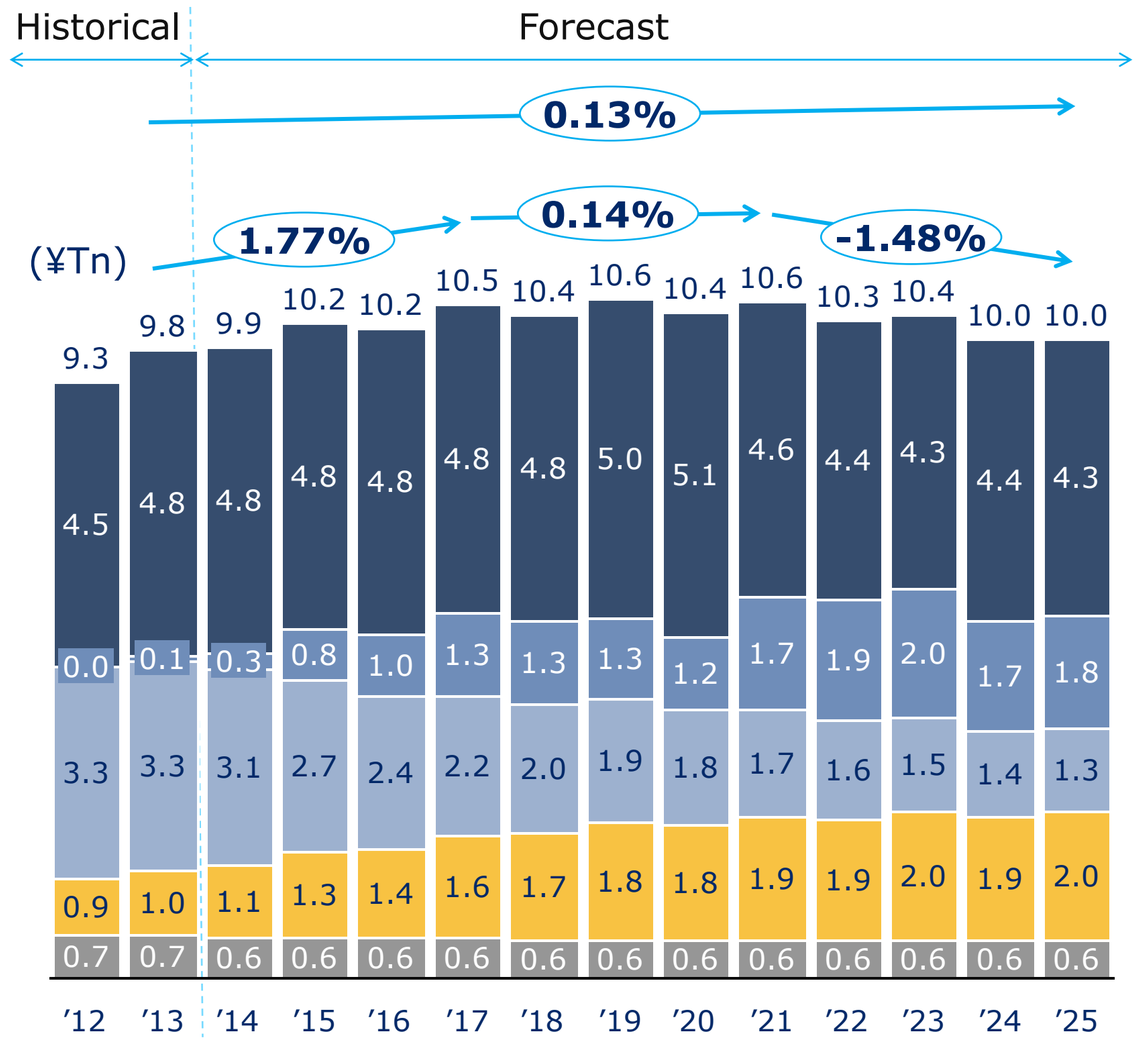
The market will grow at a CAGR of 0.52%(’13-’25), starting at 2.96% of first 3 years (with consumption tax revision)

Market growth (¥Tn)*1

Considering consumption tax revision



Not considering consumption tax revision*2



Ox | LLP (b) | LLP (a) | Gx | Others

*1 LLP (a) is the LLP whose Gx was launched before 2013, LLP (b) is the other LLP
*2 Consumption tax rate was fixed at 5% through the forecast period

Study Methodology: Overall Assumptions

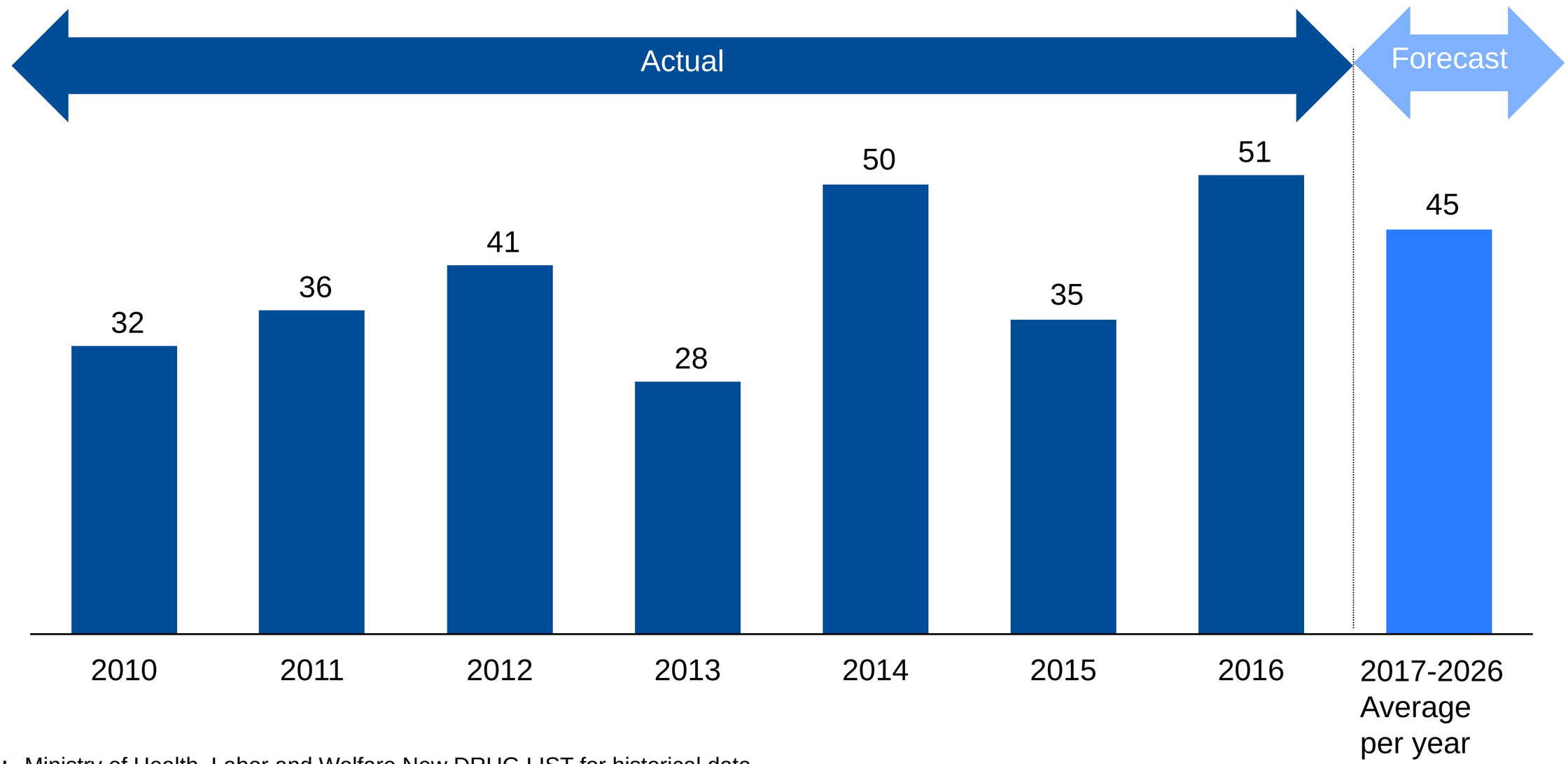
Sample, Market Forecast and New Drug Pricing Scheme etc. Assumptions

Category	Assumptions
Three product categories	Depending on the Gx situation 1) Existing drugs, Out of scope of price maintenance premium 2) Existing drugs, Possibility with price maintenance premium 3) New drugs to be launched from 2017
New launches	45 NMEs each year during 2017-2026 1/3 will be biologics drug
Estimated sales for a new product	JPY10.8 billion peak sales for small molecules/year JPY12.4 billion peak sales for biologics/year
Data: Extrapolation method	Based on data from IMS database; sales trend by ATC category*
Timing of LoE	11 years after launch
Gx penetration	Gx erosion rate will reach 80% by 2020 based on ATC category. Erosion speed will be also accelerated to reach within 10 Quarters. BS erosion rate will reach 50% within 5 years with wider variation.
Applicable drugs for premium	55% of the sales estimate of new molecules are assumed to be covered by the premium
Price revision rate	Estimated by each product category (New product with/without premium, LLPs, Gxs etc.)

* Anatomical Therapeutic Chemical Classification (category)

Total number of new drug launches is assumed to be 45 products per year in the future

Total number of new drug launch (forecast)



Source: Ministry of Health, Labor and Welfare New DRUG LIST for historical data

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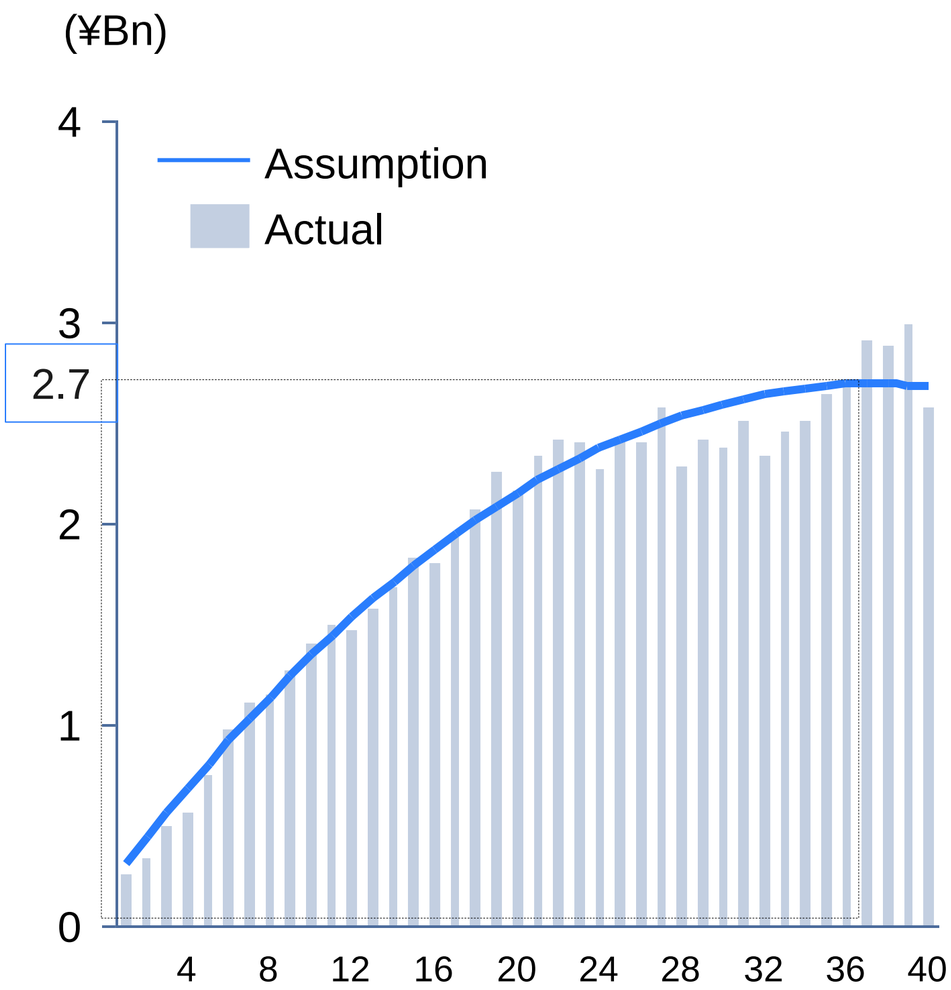
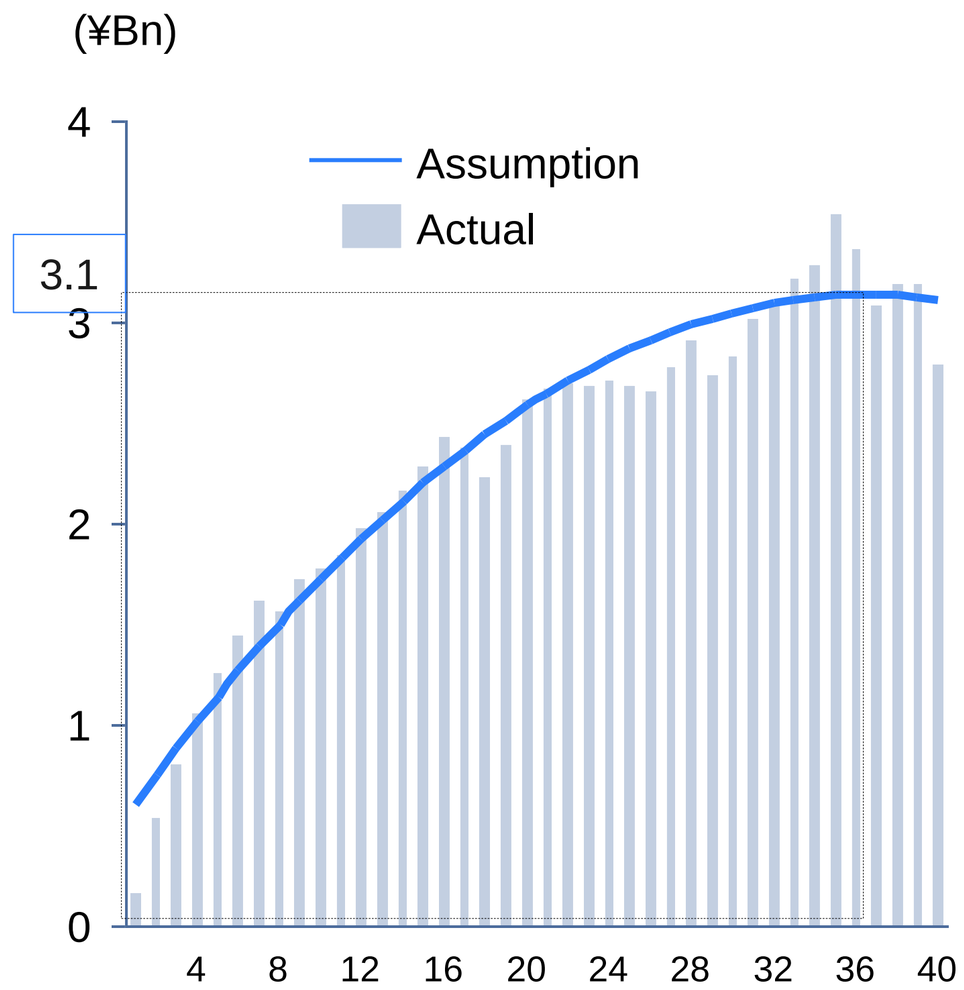
Peak sales value of low molecule drugs and biological drugs are assumed to be ¥2.7 and ¥3.1 Bn respectively

Sales of low molecule drugs (per QTR)*1



Peak sales value of low molecule drugs is assumed to be ¥2.7Bn at 37-QTRs

Sales of biological drugs(per QTR) *1



Peak sales value of biological drugs is assumed to be ¥3.1 Bn at 37-QTRs

Source: IMSBase JPM

*1 The trend line is created based on actual sales excluded Opdivo and drugs of hepatitis C and impact of new pricing premium scheme.

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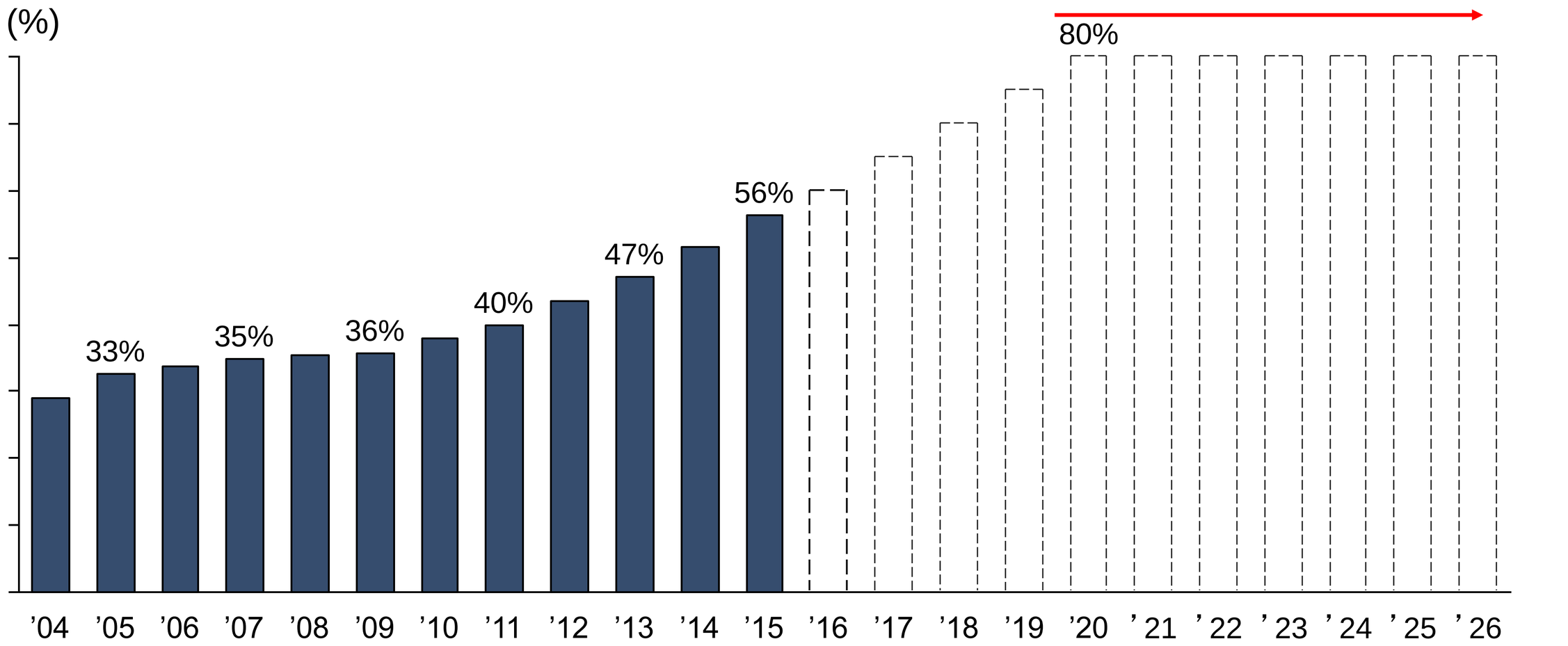
Gx penetration rate after 2020 is set to be 80% according to government goal

Gx penetration rate[*1]



Source: Ministry of Health, Labor and Welfare

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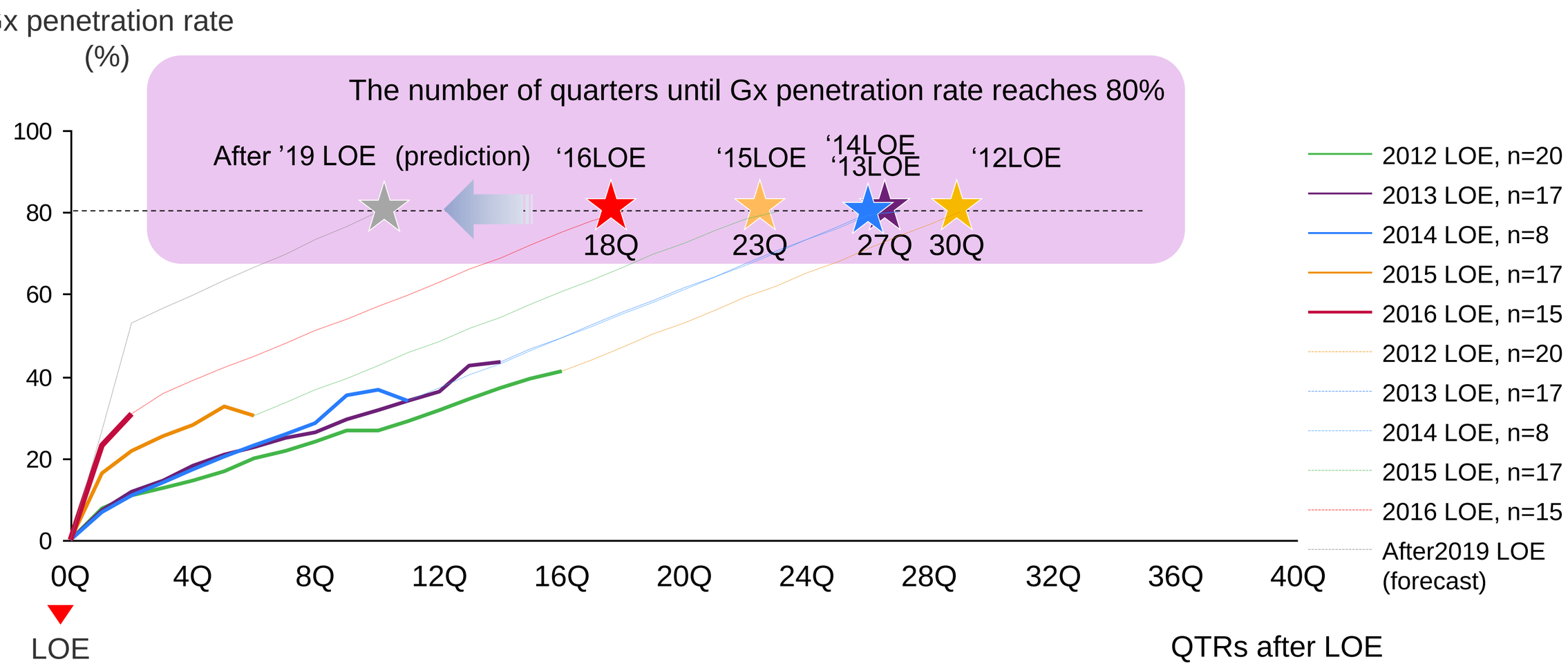
The number of quarters until Gx penetration rate reaches 80% is set based on the past trend

Assumption of Gx penetration speed



Source: IMSBase JPM

*1 Analysis on a weight basis by small classification of ATC 4 dosage form. Products whose Gx penetration rate has reached 100% was excluded

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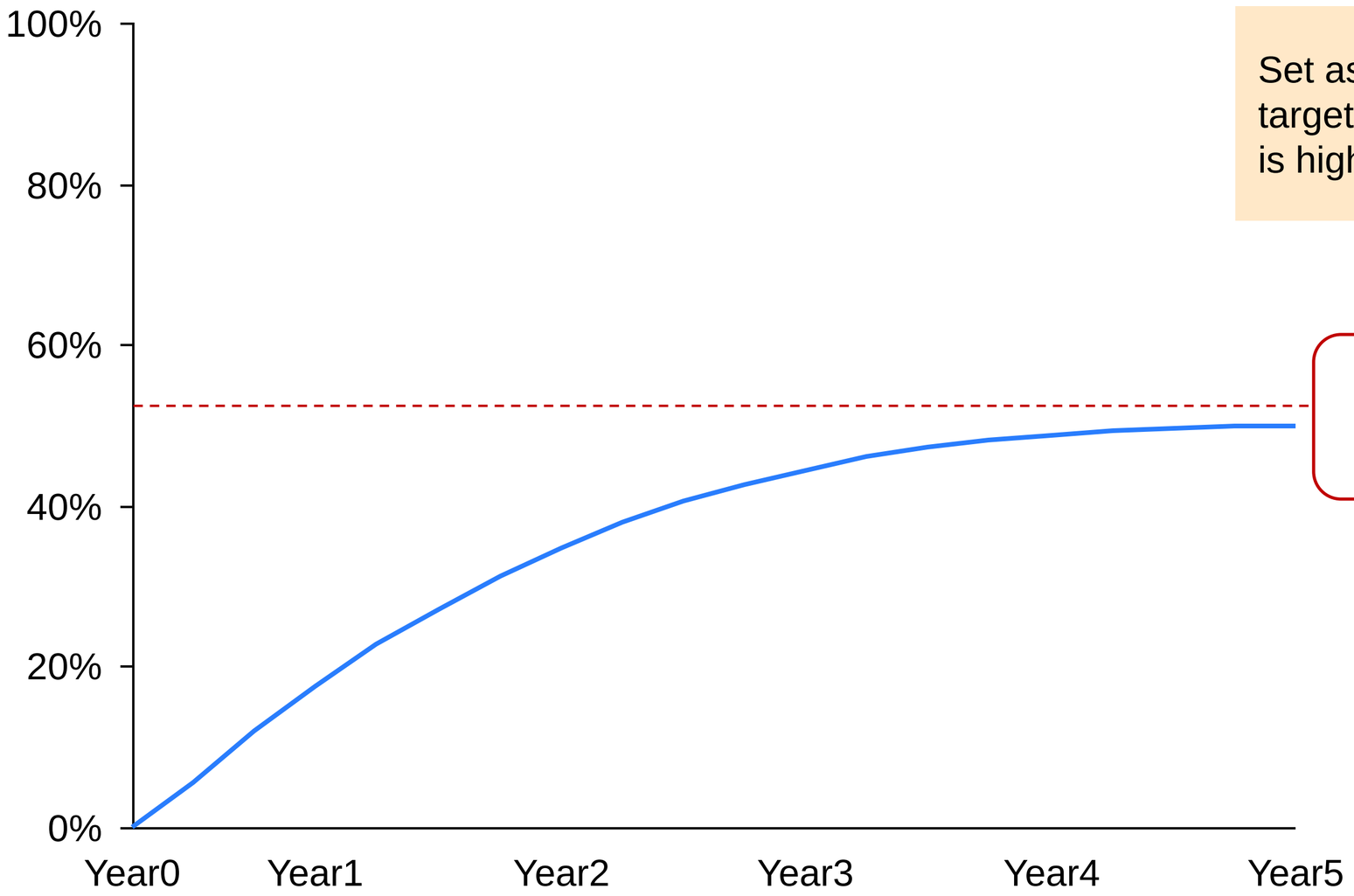
Penetration rate of BS, which will launch in the future, is set as 50% maximum in 5 years after launch

Assumption of BS penetration rate



Set as about half of the Gx penetration target of low molecular drugs, 80%, which is higher than current BS penetration rate

Penetration rate of existing BS is set individually

- ✓ Epoetin 100%
- ✓ Filgrastim 80%
- ✓ Insulin glargine 50%
- ✓ Infliximab 19%
- ✓ Somatropin 8%

*1 QuintilesIMS forecast

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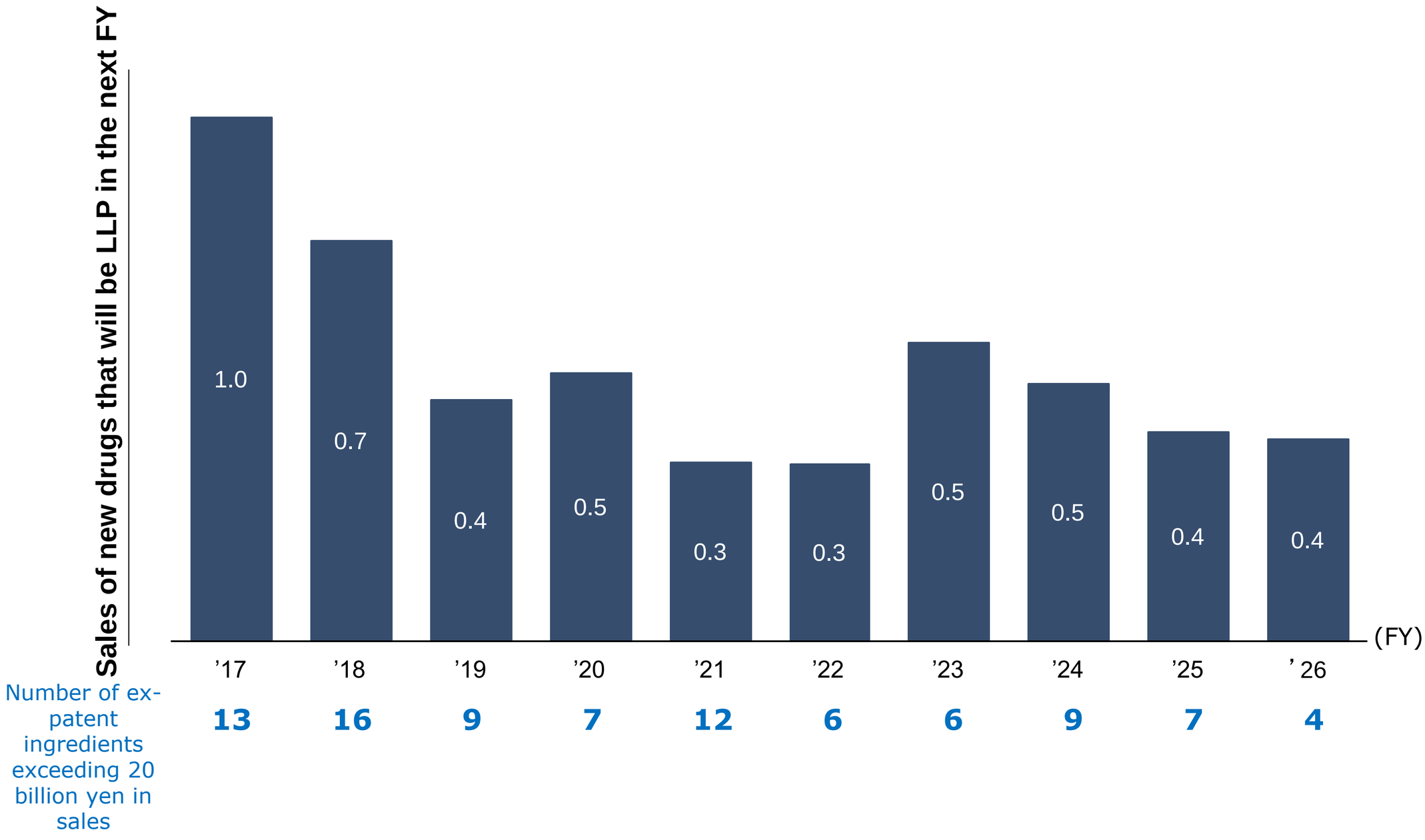
In 2017 and 2018, there will be a lot of new LLPs exceeding 20 billion yen, which will contribute significant saving money from new drug market

Sales amount of new drugs that will be LLP in the next year (Unit: ¥Tn)



Source: IMSBase JPM

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The future market is expected to change with CAGR -1.5% and to be ¥9.0 Tn in 2026

Market growth (The entire market, unit: trillion JPY) *1

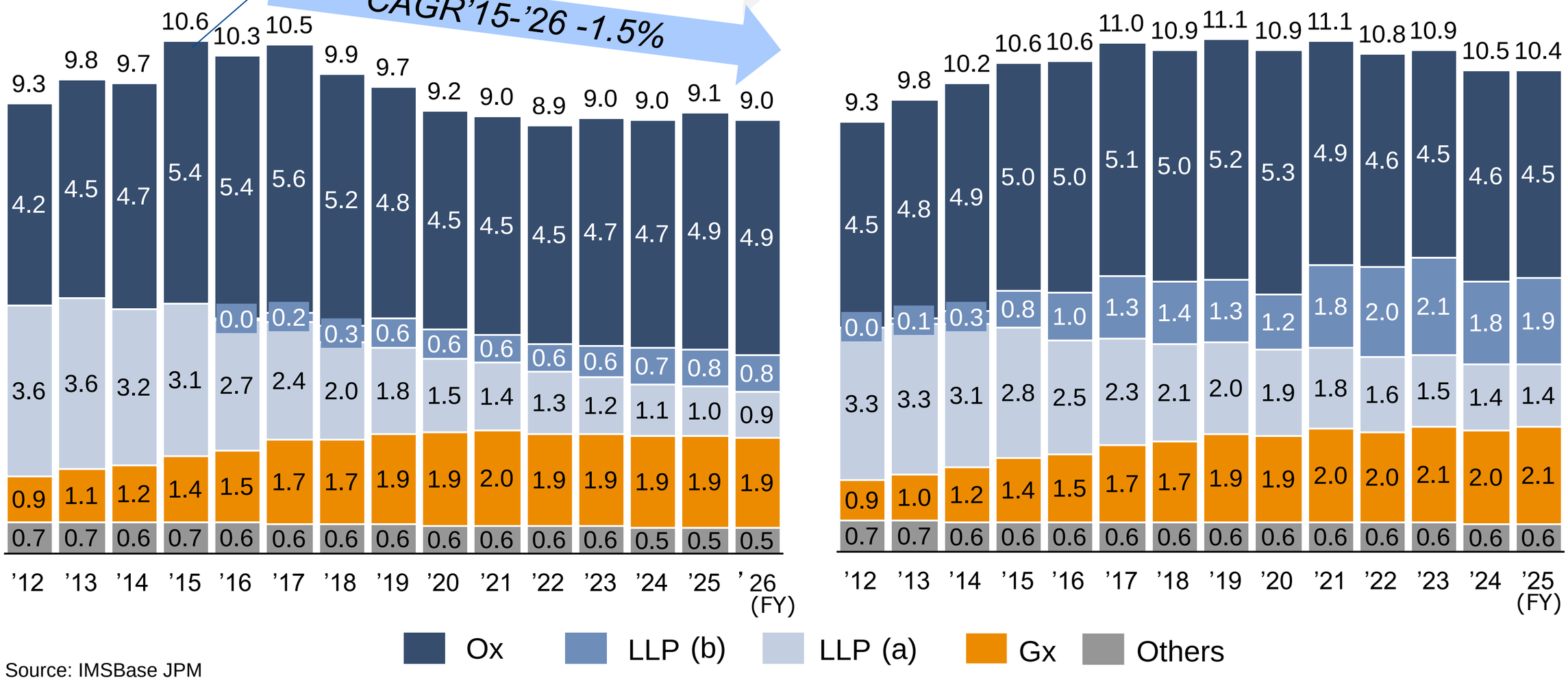
Project in 2016

(Ref.) Project in 2014

Especially, drugs for hepatitis C and antitumor agents expanded the market

CAGR'12-'26 -0.3%

CAGR'15-'26 -1.5%



Source: IMSBase JPM

*1 Ox: Original products, LLP (a): generic drugs launched before 2016, LLP (b): generic drugs launched after 2017, or planned to be launched, Gx: Generic products

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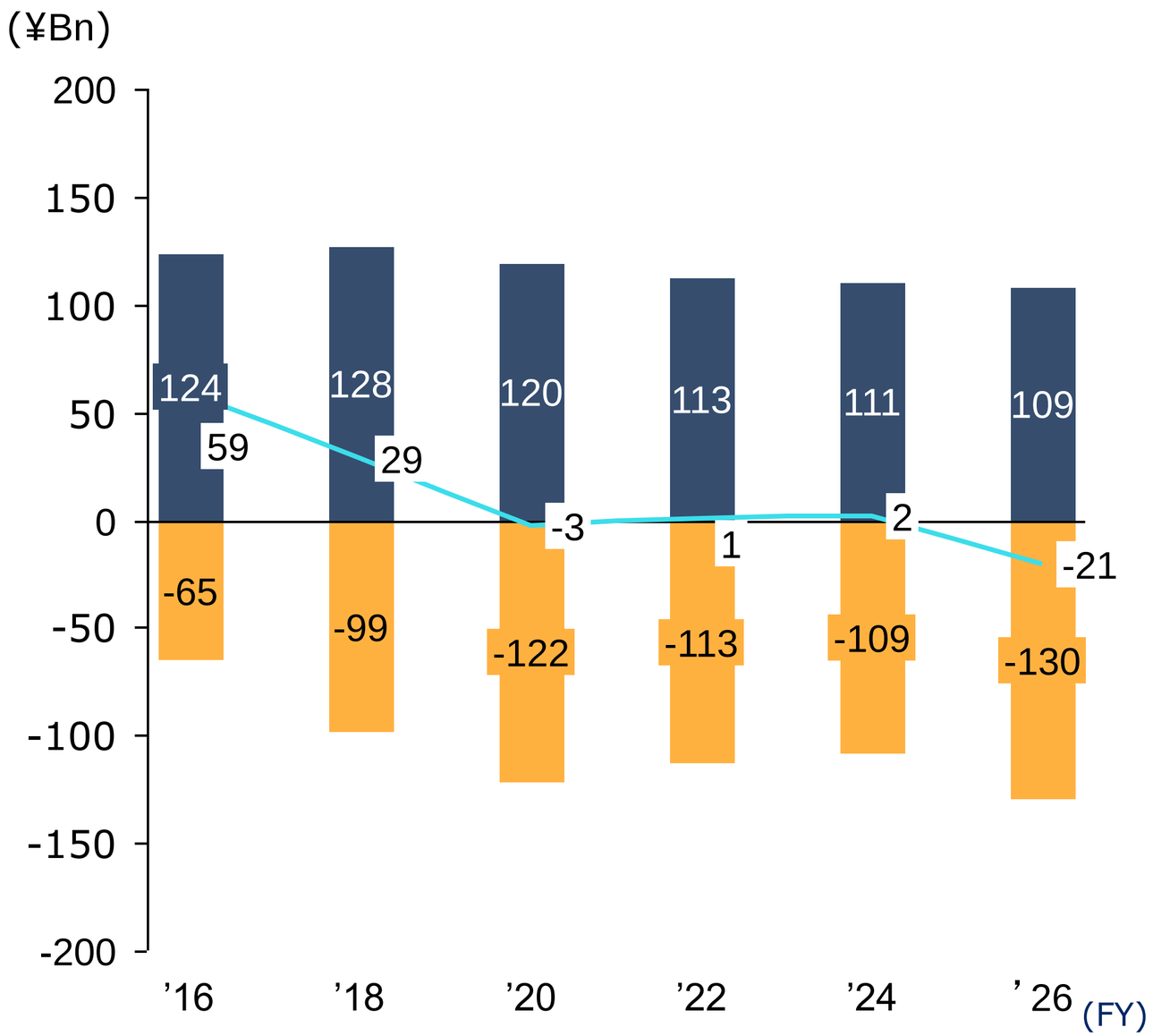
The value of premium and return by new drug pricing scheme are balanced

The value of premium value and return value by new pricing premium scheme



	Average value per NHI price revision	Sum of six NHI price revisions (2016-2026)
Premium	¥117.5 Bn	¥705 Bn
Return	¥⊿106.4 Bn	¥⊿638 Bn

Source: IMSBase JPM

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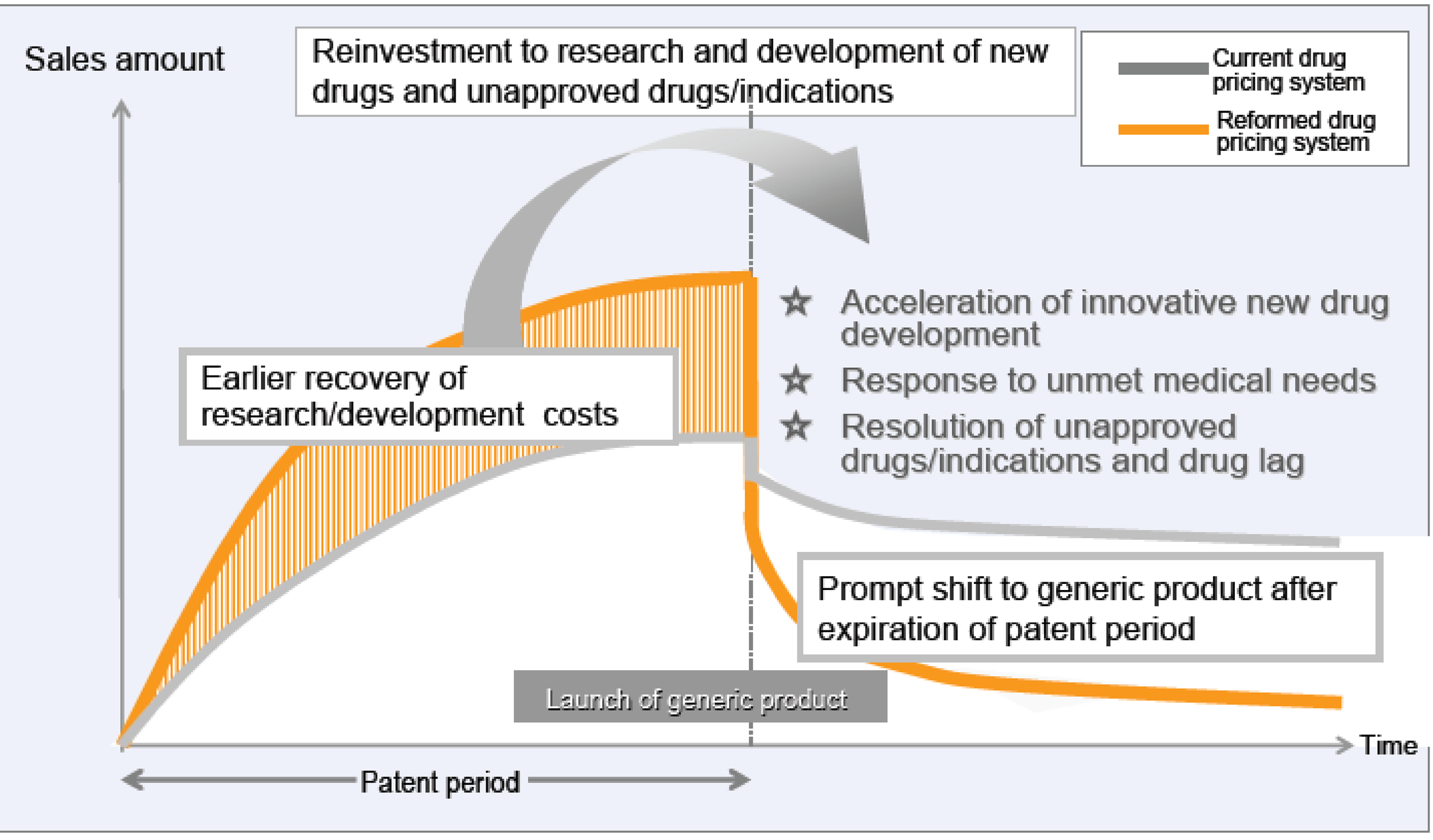
Concept of “premium for promotion of new drug creation and resolut of unapproved drugs/indications”

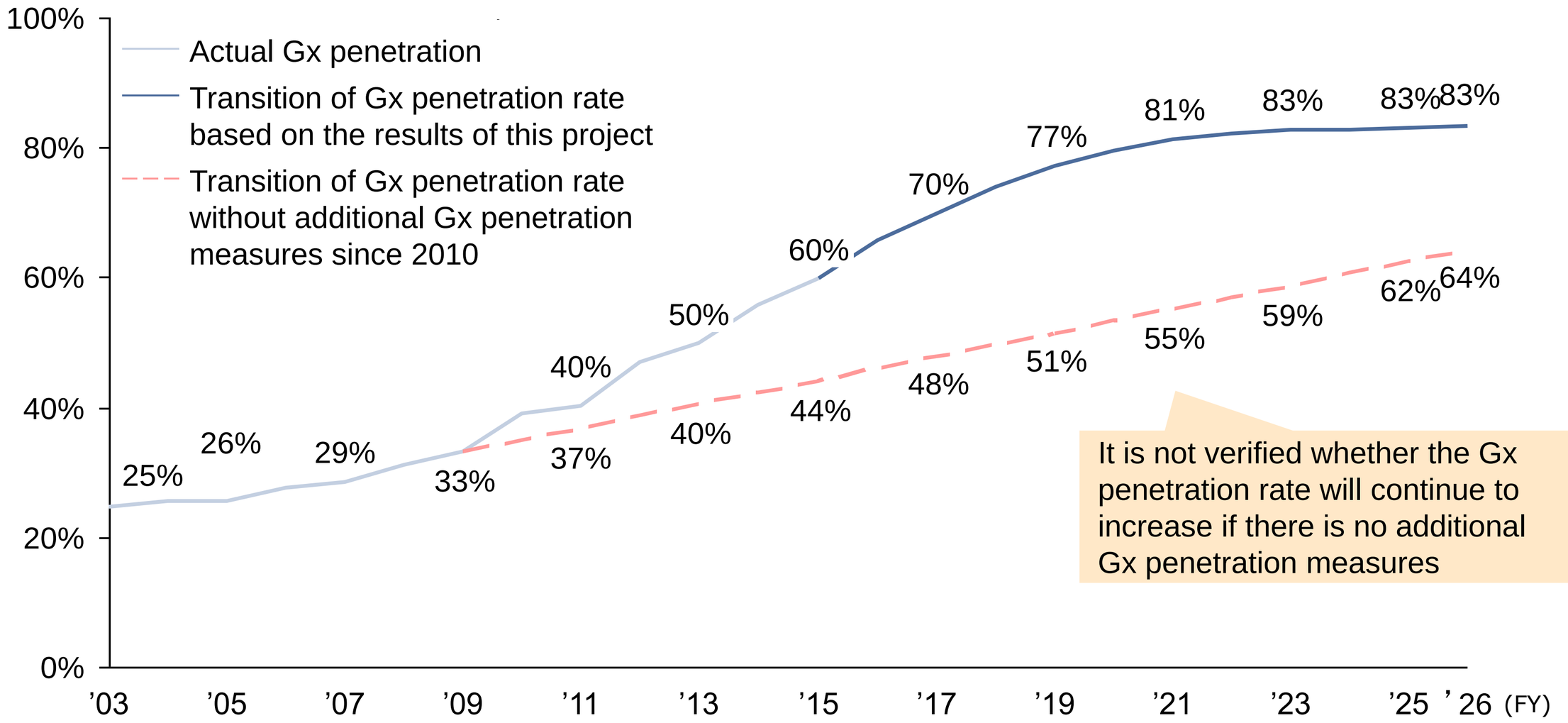
薬価制度の抜本改革に対する意見

2017年5月17日
日本製薬団体連合会
JPMA



By maintaining the price (premium pricing) of the forerunner product in the patent period, the resource for next development can be secured earlier, enabling promotion of development of new drugs and unapproved drugs/indications and earlier responses to needs of patients and healthcare professionals.

In the impact analysis of Gx penetration measures, Gx penetration rate without additional measures is set as follows



- In the case of no additional Gx penetration measures after 2010, historical growth of Gx penetration before 2010 is applied. Impact of additional Gx penetration measures is calculated as difference between sales with and without additional Gx penetration measures

Source: IMSBase JPM

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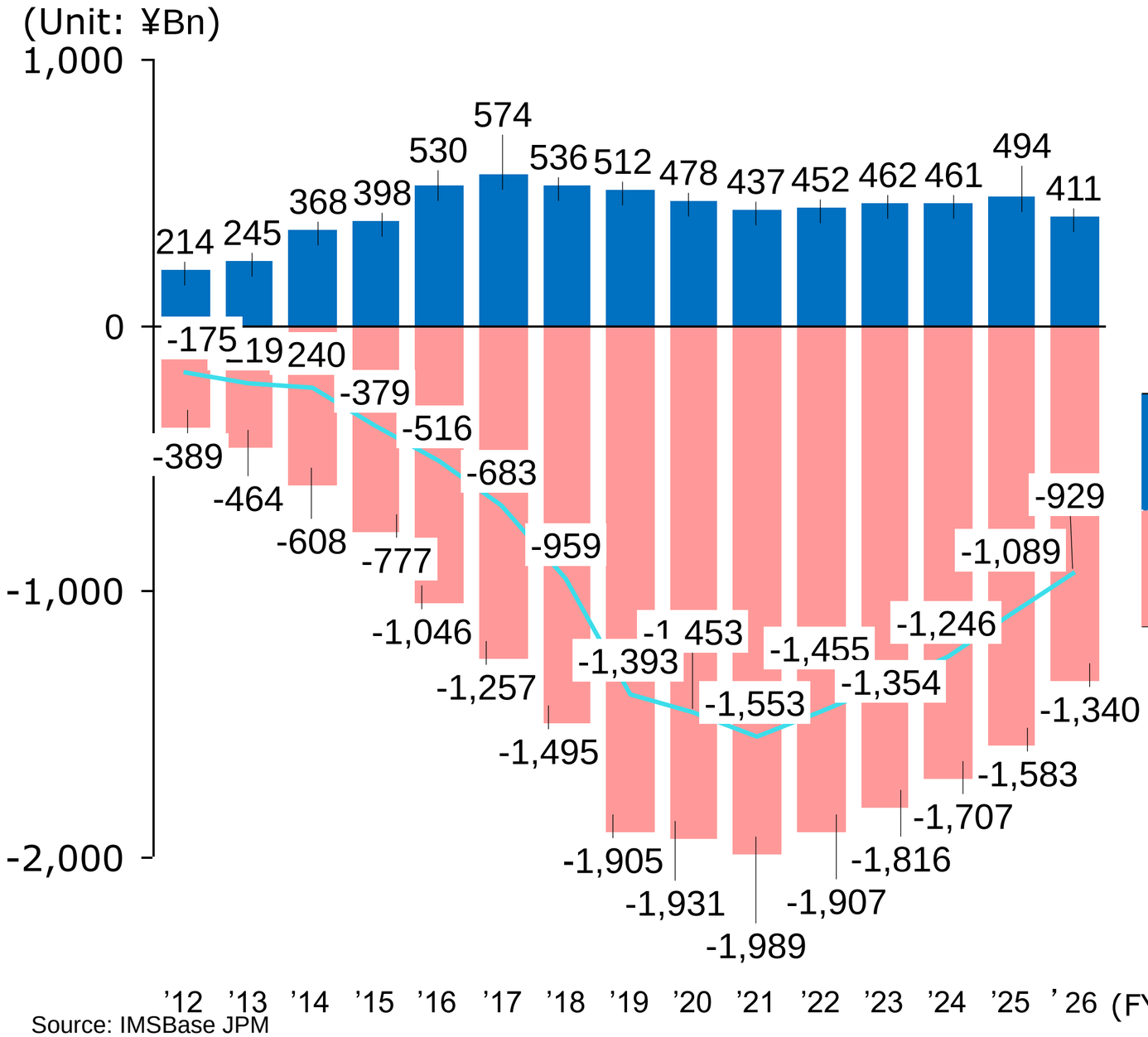
The impact on drug expenditure by new pricing premium scheme is assumed to be limited compared with additional measures

Impact of new pricing premium scheme and additional Gx penetration measures on drug expenditure



Increase in drug expenditure by new pricing premium scheme

Reduction of drug expenditure by additional Gx penetration measures *1

Impact balance

	Average impact per year	Impact value Total (2012-2026)
Increase in drug expenditure	¥438 Bn	¥6,572 Bn
Reduction of drug expenditure	¥⊿1,348 Bn	¥⊿20,214 Bn

Source: IMSBase JPM

*1 In the case of no additional Gx penetration measures after 2010, historical growth of Gx penetration before 2010 is applied. Impact of additional Gx penetration measures is calculated as difference between sales with and without additional Gx penetration measures

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In addition to base scenario, high and low scenario are explored

		Low	Base	High
Important events	1 Launch of highly innovative drugs	-	-	¥500 Bn/ year at peak Peak at 38Q from 2018
	2 Extent of new drug pricing scheme after 2018	0%	**55%**	100%
	3 # of new launches per year	40	**45**	50
	4 Extent of annual revision	Gx/ LLP with price deviation within NHI price and wholesaler price is less than Some difference**	**Gx/ LLP with price deviation within NHI price and wholesaler price is** Large difference**	-
	5 Acceleration/ deceleration of Gx penetration speed	-	**10Q**	14Q

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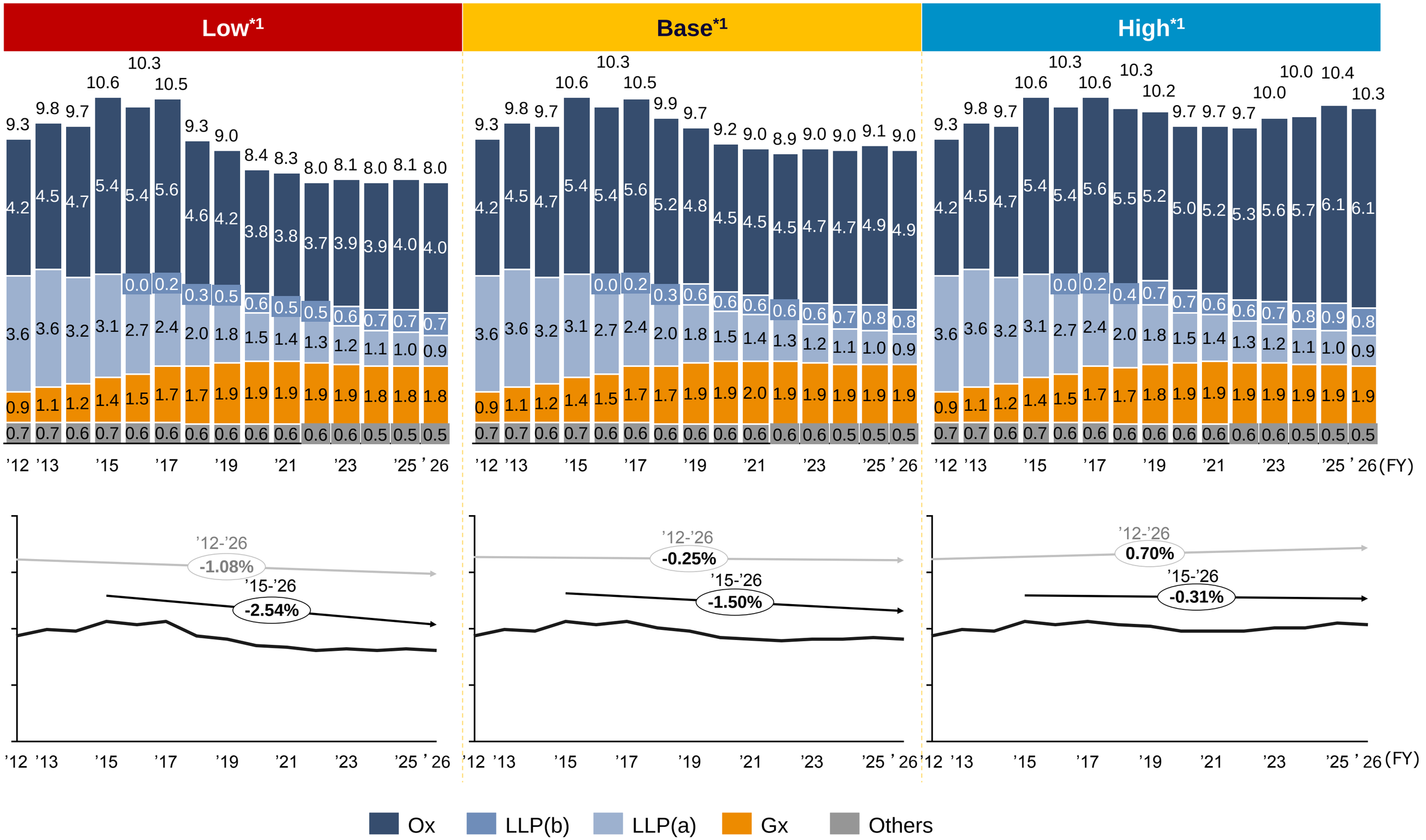
The Ox market in 2026 will be ¥6.1 Tn by high scenario. On the other hand, it will be ¥4.0 Tn by low scenario



Source: IMSBase JPM

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Results: The Simulation Predicts negative growth of drug market

<u>Key Learnings from the result of this simulation:</u>
While a certain new drug market is creating every year came from the promotion of new drug development, LLP market will shrink drastically based on the promotion of Gx use. Total drug market will have negative growth in coming 10 years.

- **Drug market:**
  - **The compound annual growth rate (CAGR) of drug expenditures will be -1.5% in the next 10 years**
  - **The ethical drug market will estimated at 9.0 trillion yen in 2026 from 10.6 trillion yen in 2015**

- **Policy measurements:**
  - **Drug expenditure will not be the main factor of increase of healthcare expenditures**
  - **The expense increase by price premium is estimated to be limited than the expense reduction by Gx promotion**
  - **Gx market share will increase to 80% by 2020 with the premium pricing system.**

Conclusion: EFPIA Addresses Price Maintenance System During Patent Period and More Rewarding Innovation

Key Issues:

The premium pricing rule facilitates innovation itself as well as rewarding innovation without increasing total drug expenditures

- **Current Healthcare System:**
  - **Drug development in Japan has been earlier and more activated**
  - **The promotion of generics has brought huge efficiency rather than rewarding innovation**
  - **Current pricing system is working well with balanced way for facilitating innovation leads patients' benefit and controlling drug costs for Japanese government**
  - **The drug market is estimated negative growth and there will be a large room to reward for innovation from saving from efficient measures**
- **Our proposal:**
  - **EFPIA strongly believes the possibility of compatibility of cost saving and rewarding innovation to encourage innovation, secure access, and contain the increase of costs,**
  - **EFPIA strongly recommends the price maintenance system in addition to more rewarding innovation.**

Supportive slides

Study Methodology: Introduction

EFPIA/QuintilesIMS conducted a simulation study into drug expenditures

Underlying factors and assumptions

- **The new premium pricing rule imposes a one-time payback (price reduction) at the time of loss of exclusivity (LoE) to compensate for previous exemptions.**

- **Generic erosion rate as well as its speed has been accelerated by the political measure.**

- **While new products (small molecule and biologics) will be surely launched, major low molecule products will face patent off and will be switched to Gxs and BSs.**

- **Assumptions were made on:**
  - **New products launches (# of new products, its peek sales)**
  - **NHI drug price reduction rate**
  - **Gx penetration ratio and trend**
  - **Timing of Gx entry**
  - **etc.**

(Ref.) Difference of Assumption of 2014 and 2017 Project

Difference between Assumption of 2014 Project and of 2016 Project				
			2014 Project*1	2016 project
Volume	Goal of Gx penetration rate		•In 2016, 60% on a Volume basis	•In 2020, 80% on a Volume basis
	Cat2	Volume	•Estimated based on past trends by ATC	•In products within 7Q after launch, past trends by ATC is used. •In products over 8Q after launch, current CAGR is applied until 40Q and CAGR decreases gradually after 40Q.
		Peak % of Gx penetration	•About 60%	•About 80%
		# of QTR to reach peak Gx penetration	•More than10Q (Set by each ATC)	•10Q
	New drug of Cat3	# of new launches per year	•45 molecules per year	•45 molecules per year
		% of biological drug	•29% in 2015, 32% in 2016, 33% after 2017	•25%
		# of QTR to reach peak volume	•20Q	•37Q
		Extent of new pricing premium	•81% on a sales basis	•55% on a sales basis
Value	Price at time of listing	Sales of new drugs	•Low molecular drugs: ¥2.5Bn/ Q •Biological drugs: ¥2.0Bn/ Q	•Low molecular drugs: ¥2.7Bn/ Q •Biological drugs: ¥3.1Bn/ Q
		NHI price of Gx	•51% of Ox	•41% of Ox
	Revision rate	Ox in regular revision	•6.3%	•7.3%
		Gx in regular revision	•18~19%	•8~28%
		LLP in regular revision	•7.4%	•8.2%
		Z2 rule	•Gx penetration 0-20%: 2.0% •Gx penetration 20-40%: 1.75% •Gx penetration 40-60%: 1.5%	•Gx penetration rate 0-30%: 2.0% •Gx penetration 30-50%: 1.75% •Gx penetration 50-70%: 1.5%
		Annual revision	•(Not considered in base scenario)	•Gx/LLP with price deviation within NHI price and wholesaler price is less than Large difference**
	Consumption tax increase		•10% in 4Q 2015	•(Not considered)
	Market expansion recalculation		•0.37% at regular revision	•0.50% at regular revision

Source: IMS Forecast of Japanese pharmaceutical market 2014

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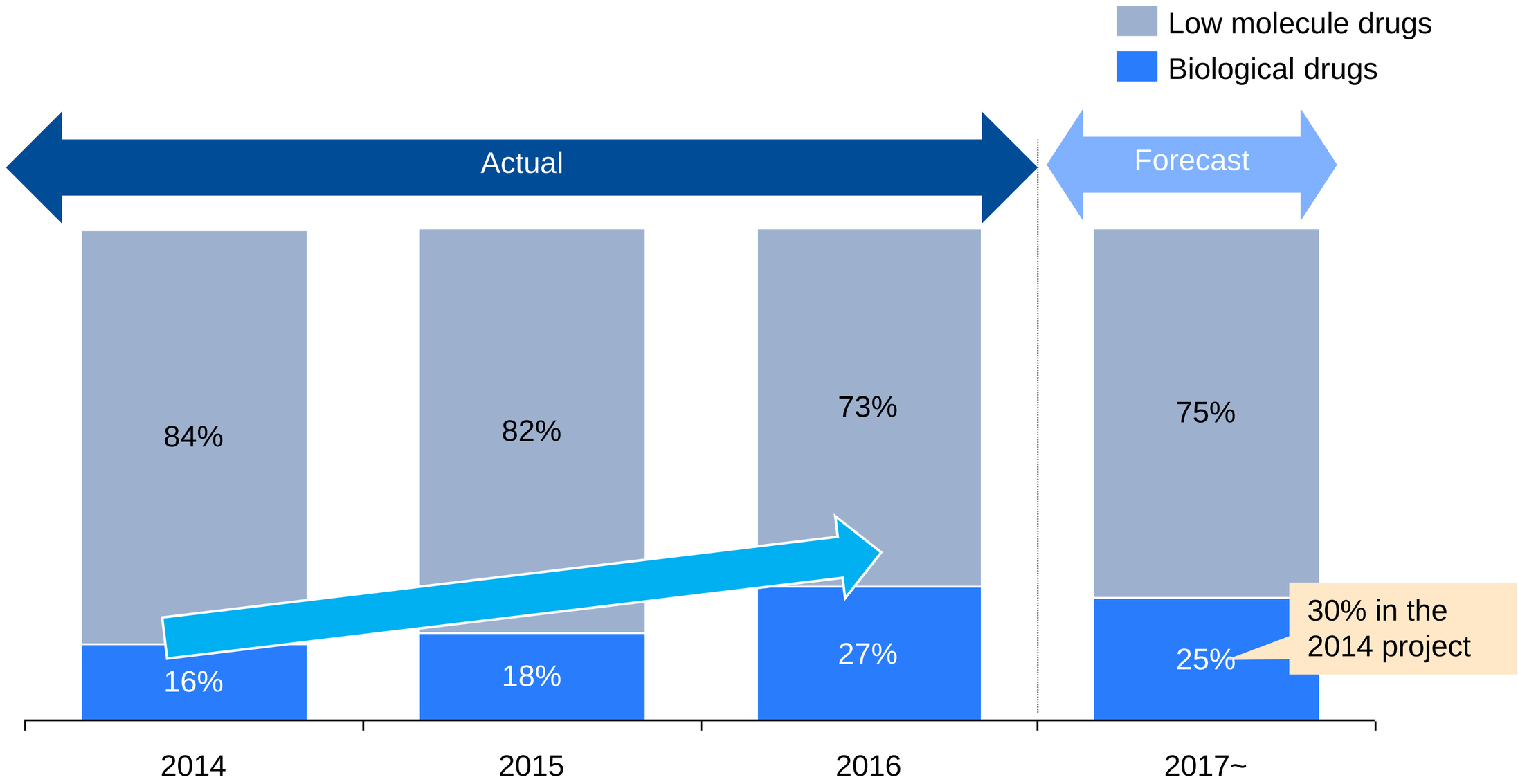
% of future biological drug is assumed to be 25% based on past trends

Percentage of biological drugs in approved number



Source: Ministry of Health, Labor and Welfare New DRUG LIST for historical data

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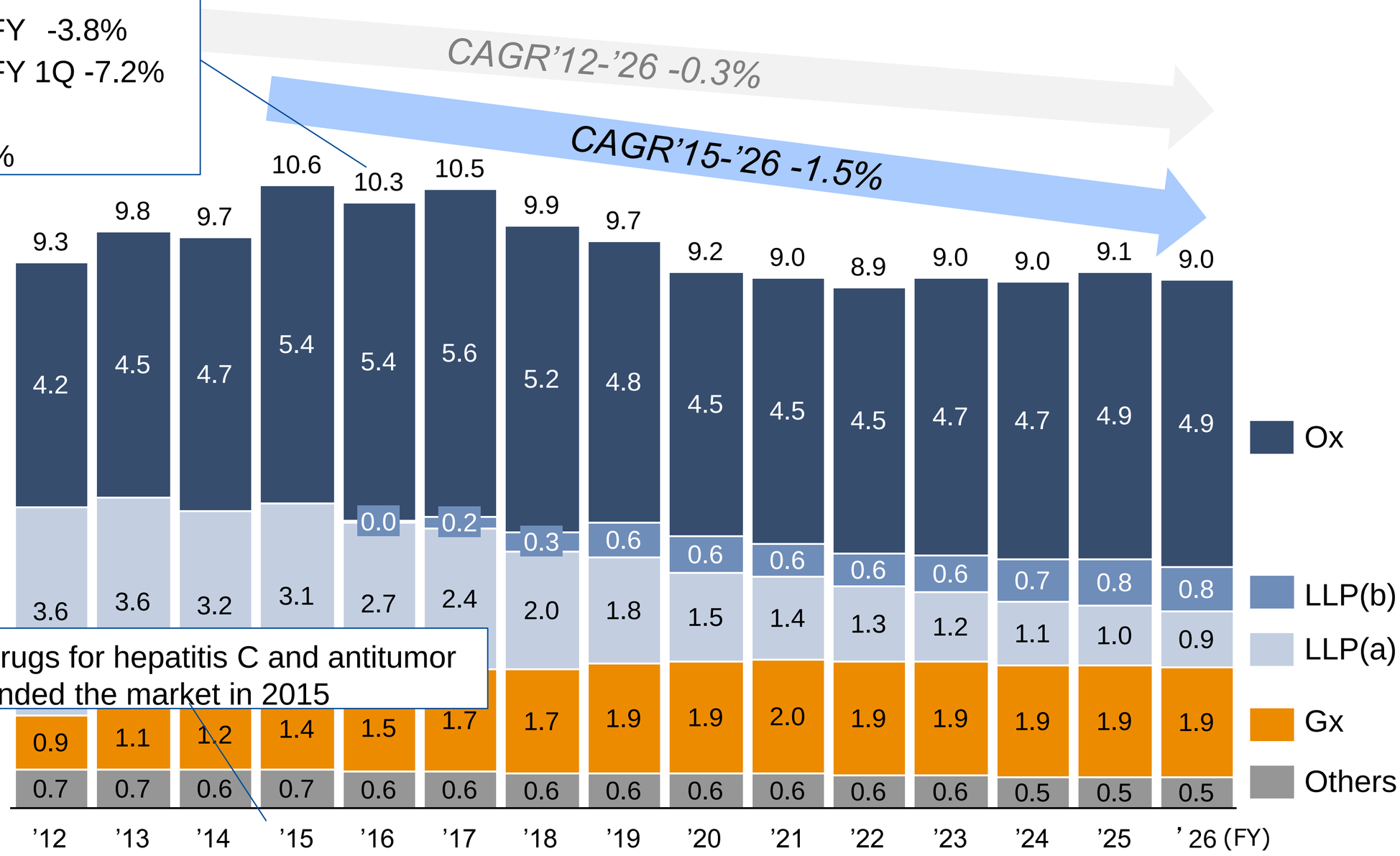
The future market is expected to change with CAGR -1.5% and to be ¥9.0 Tn in 2026

Market growth (The entire market, unit: ¥Tn) *1

- Japan
  - ✓ 2016FY -3.8%
  - ✓ 2017FY 1Q -7.2%
- World
  - ✓+6.9%



Especially, drugs for hepatitis C and antitumor agents expanded the market in 2015

Source: IMSBase JPM

*1 Ox: Original products, LLP (a): generic drugs launched before 2016, LLP (b): generic drugs launched after 2017, or planned to be launched, Gx: Generic products

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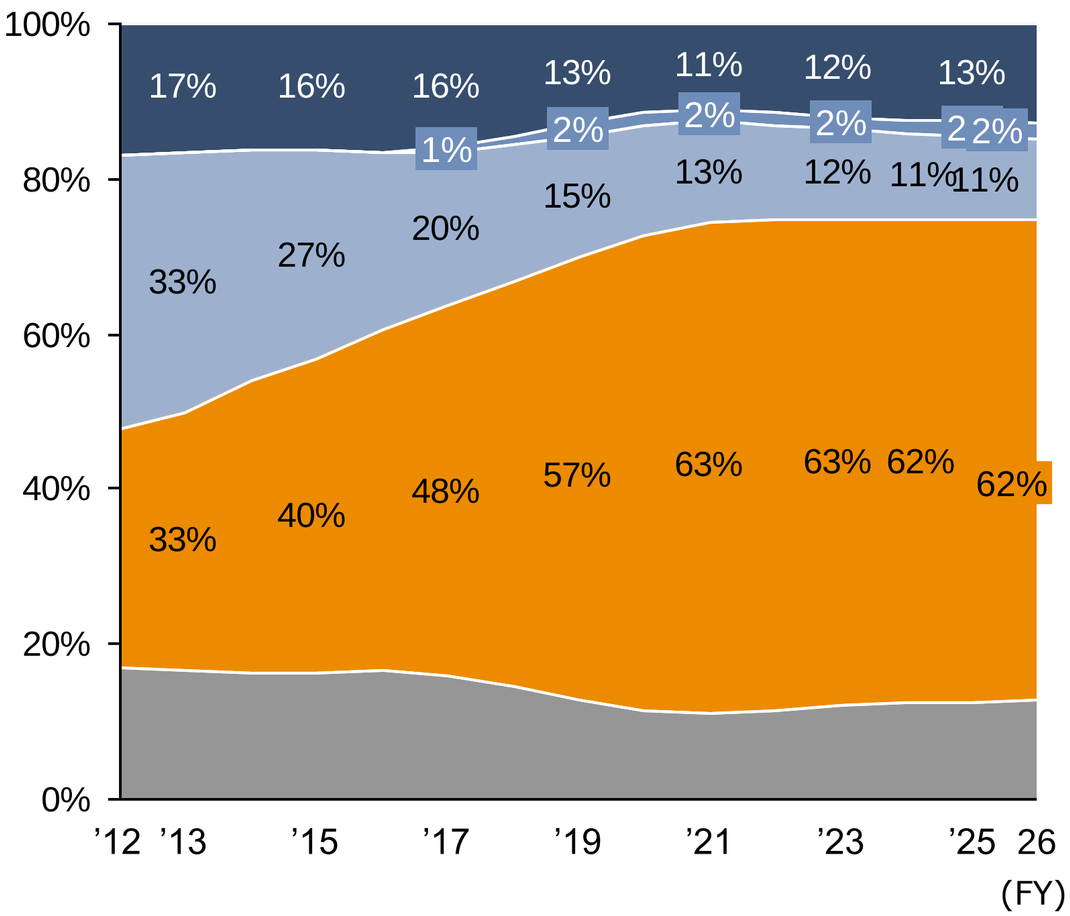
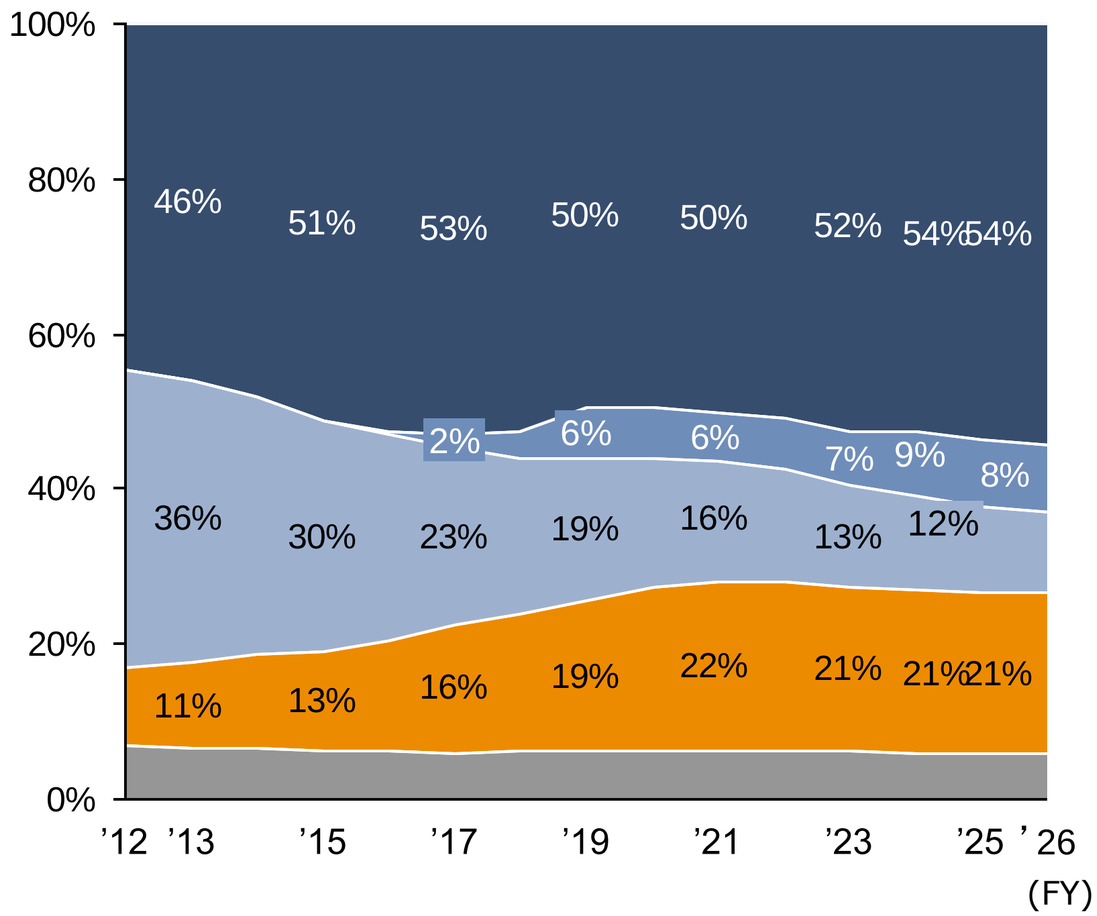
While % of Gx increases both in volume and sales, LLP is expected to shrink significantly

Market composition*1

Volume basis



Value basis



Ox LLP(b) LLP(a) Gx Others

Source: IMSBase JPM

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