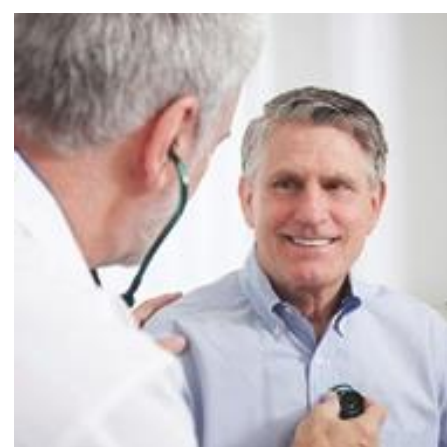




European Federation of Pharmaceutical
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EFPIA-Japan and IMS drug market forecast for Japan based on current drug pricing policy proposals



31 May, 2017
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Chair, EFPIA Japan



Lessons from the drug market forecasts

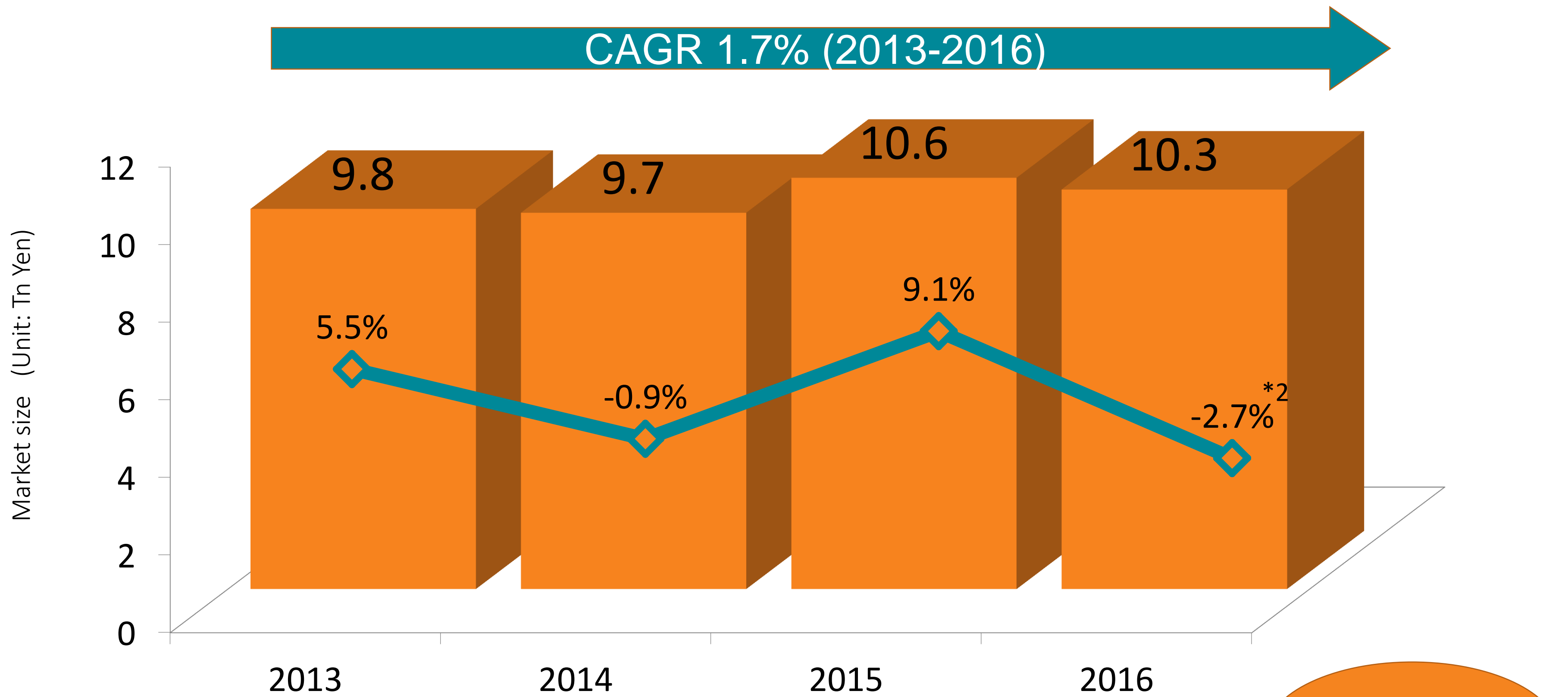
The drug market in Japan will be flat or slightly declining over the next decade

Japan likely to be the lowest growing market among major markets

The analysis clearly suggests: Japan can continue to reward innovation AND make budget savings



The drug market in Japan has grown only modestly in recent years



Source: IMSBase JPM

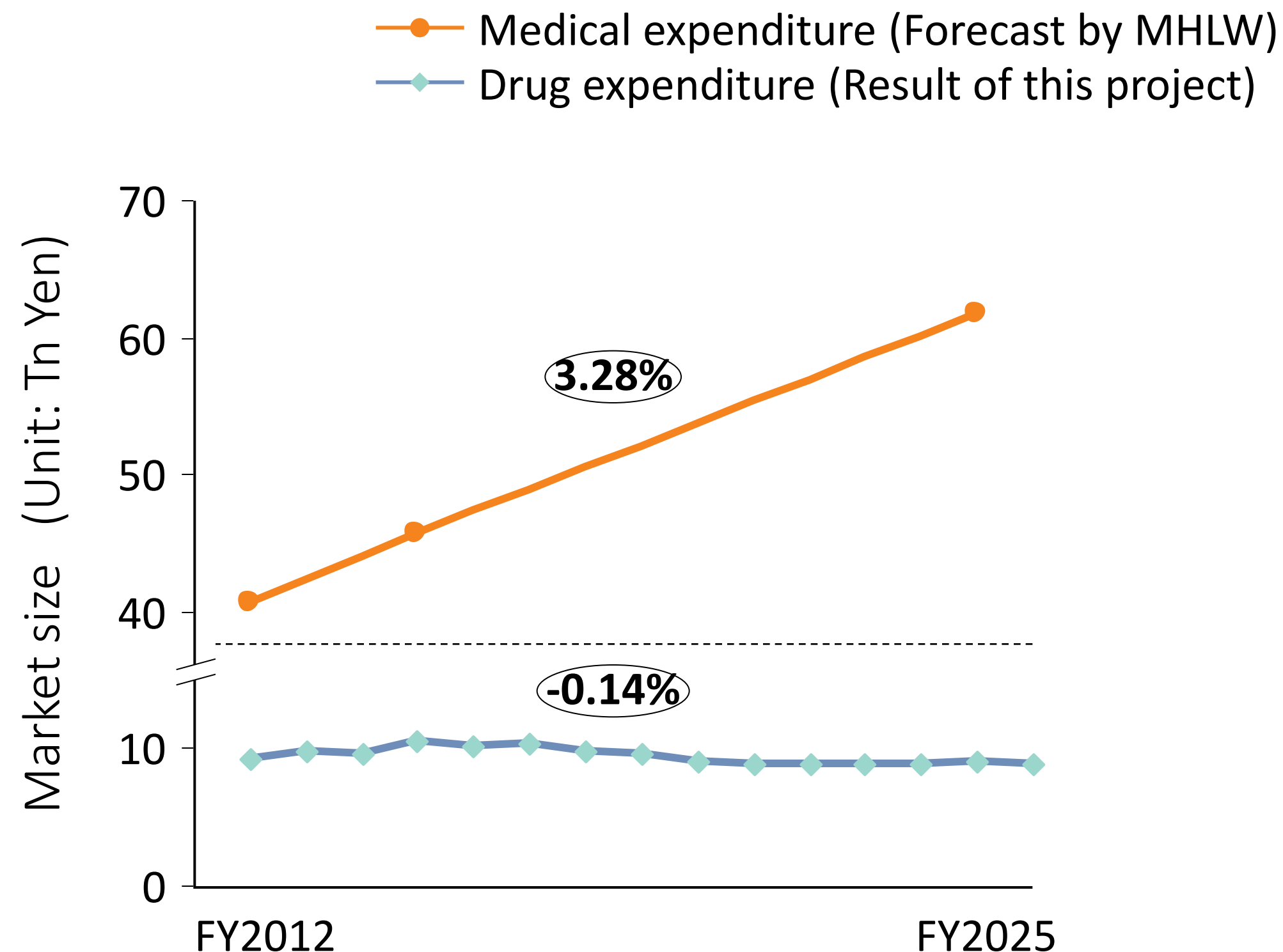
*1 EFPIA-QuintilesIMS Forecast

*2 Forecast since project started before end of FY 2016.

Actual figure was -3.6%

Drug budget is only 20-25% of healthcare spending, and is growing more slowly than the other 75%+

Market growth (comparison b/w medical expenditure and drug expenditure)*^{1,2}



Source: IMSBase JPM, MHLW Social Security Council Medical Insurance Committee,

*1 "References II on National Assembly for Social Security System Reform 'Arrangement of discussion' (Medical / nursing care field)", 2013/5/16

*2 Recalculation of Quintiles IMS estimation of drug expenditure 2016-2026, "Base" scenario forecast on this project, adjusting time period and including real data for 2012-2015

New drug prices in Japan are now low by international comparison

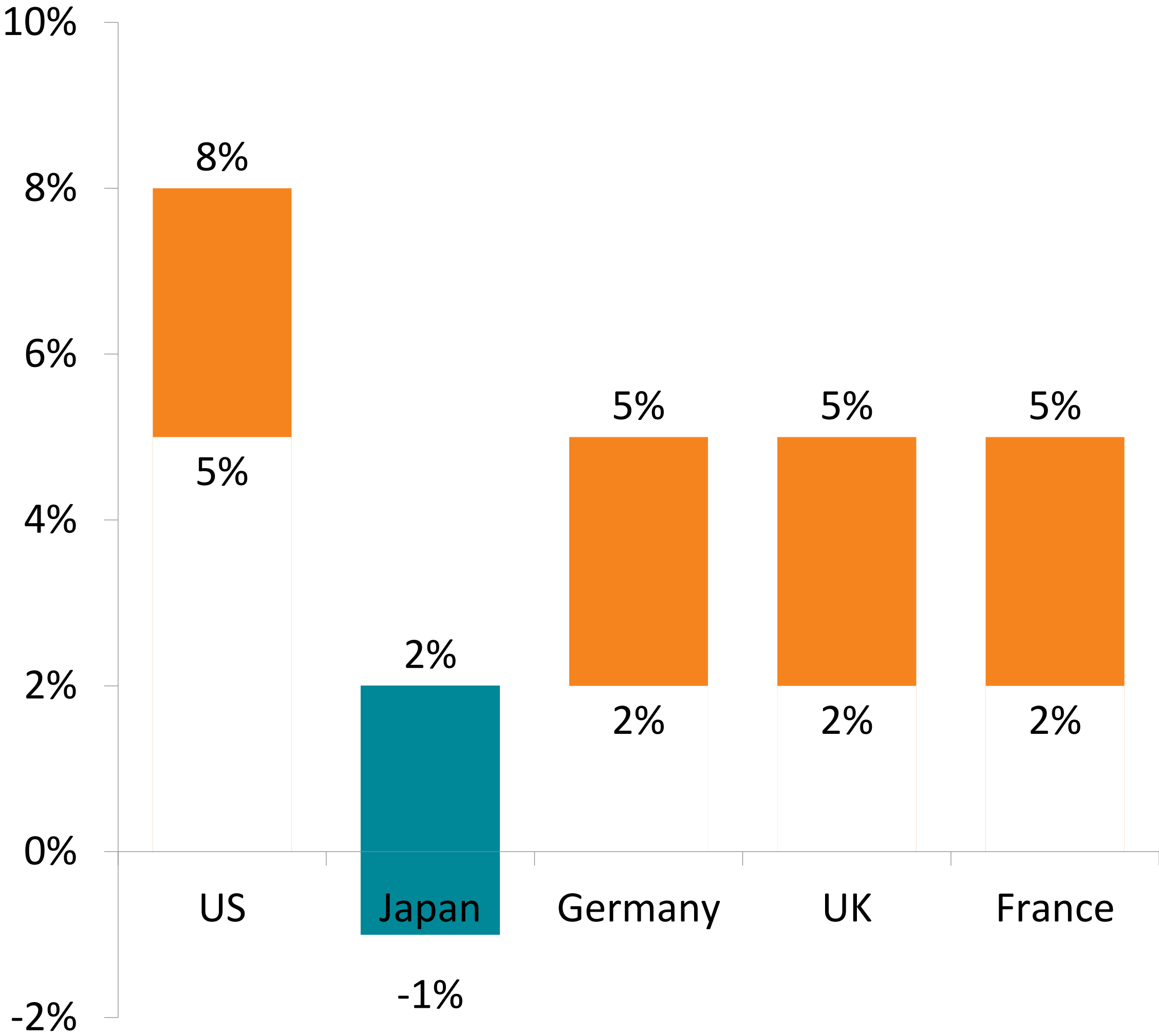
Comparison of Median Prices between Japan, EU3, and US

		2011	2012	2013	2014	2015	2016
 vs. 		+13%	+25%	+3%	-20%	-20%	-11%
 vs. 		-6%	-5%	-36%	-23%	-27%	-31%

Note: Analysis of new products listed in Japan from 2011 to August 2016 that are also listed in France, Germany, or the UK (n = 146). EU3 price is the average price across France, Germany, and the UK. US price reflects the average manufacturer rebate on branded products in Medicare Part D (35%) as estimated by the IMS Institute. Foreign currency rate is based on moving average in the year before listing in Japan, consistent with MHLW methods.

Source: IMS Institute, 2016, Estimate of Medicare Part D costs after accounting for manufacturer rebates;

Japan will be the market with the lowest growth



CAGR 2016 – 21	
US	5~8%
Japan	-1~2%
Germany	2~5%
UK	2~5%
France	2~5%
Italy	2~5%
Spain	1~4%
Canada	2~5%
Developed	2~5%
China	6~9%
Brazil	6~9%
India	10~13%
Russia	6~9%
Turkey	10~13%
Mexico	3~6%
Emerging	6~9%

Source: QuintilesIMS Market Prognosis 1Q 2017

* 1 Forecast by unified model for all countries. Forecasting methods and market definitions are

different from EFPIA-QuintilesIMS forecast

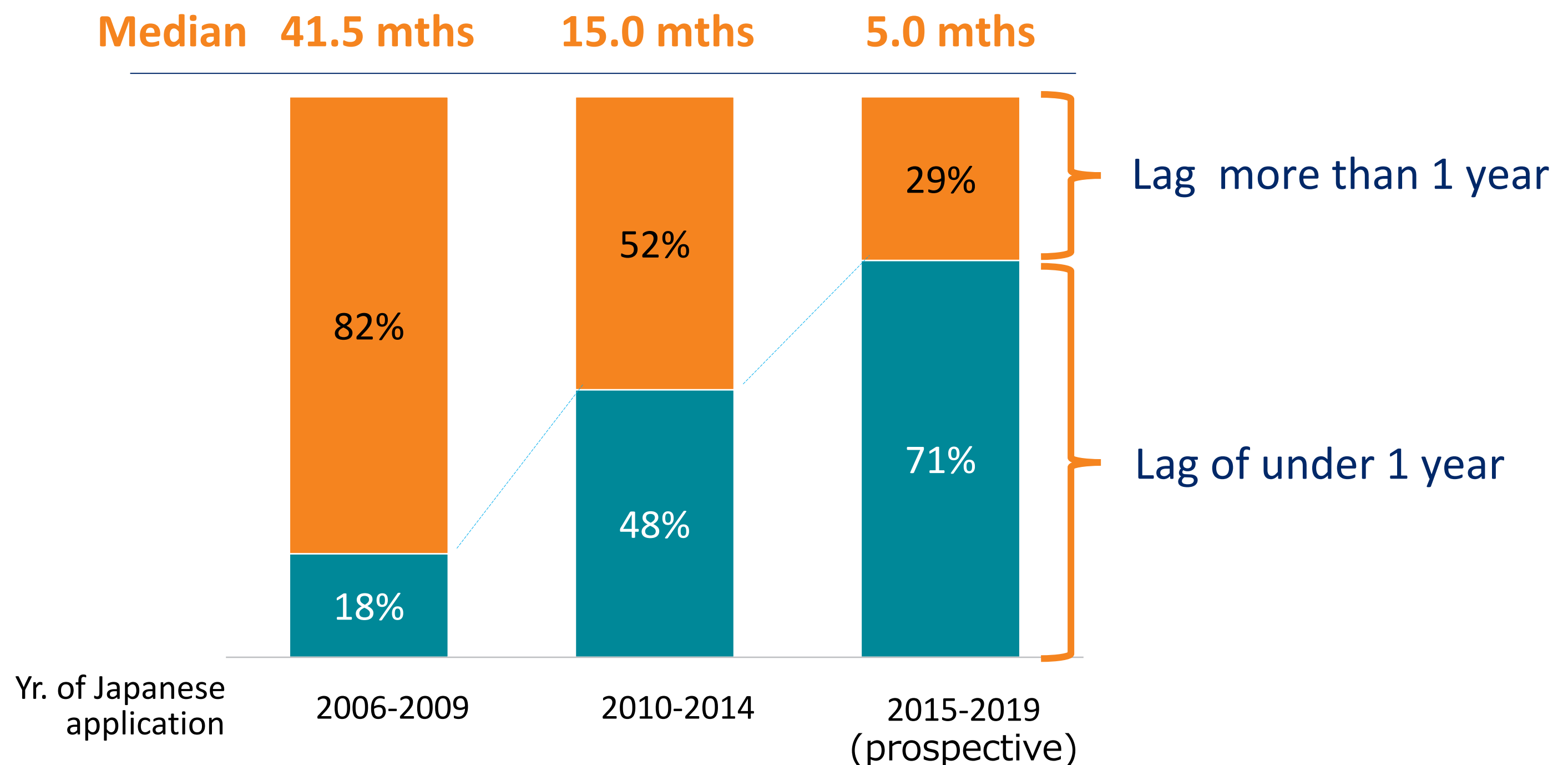
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The Price Maintenance Premium has worked! (1)

The Drug Lag has been reduced considerably

Application lag – current status and future trend *1,2



*1 Covers the 27 respondents with products applied for or to be applied for in Japan (excluding products subject to a development request etc.)

*2 Covers those of the above products with an identifiable application lag

[Source] 'Follow-up survey on impact on new drug development of the price maintenance scheme' (PhRMA) conducted at the end of 2014 on 29 major Japanese, US and European firms

[Definition of terms] Application lag: The delay (in months) in the filing of an applications in Japan following the earliest application filed amongst the countries of the US and EU5 (UK, France, Germany, Italy and Spain)

The Price Maintenance Premium has worked! (2)

Investment in development in Japan has risen considerably

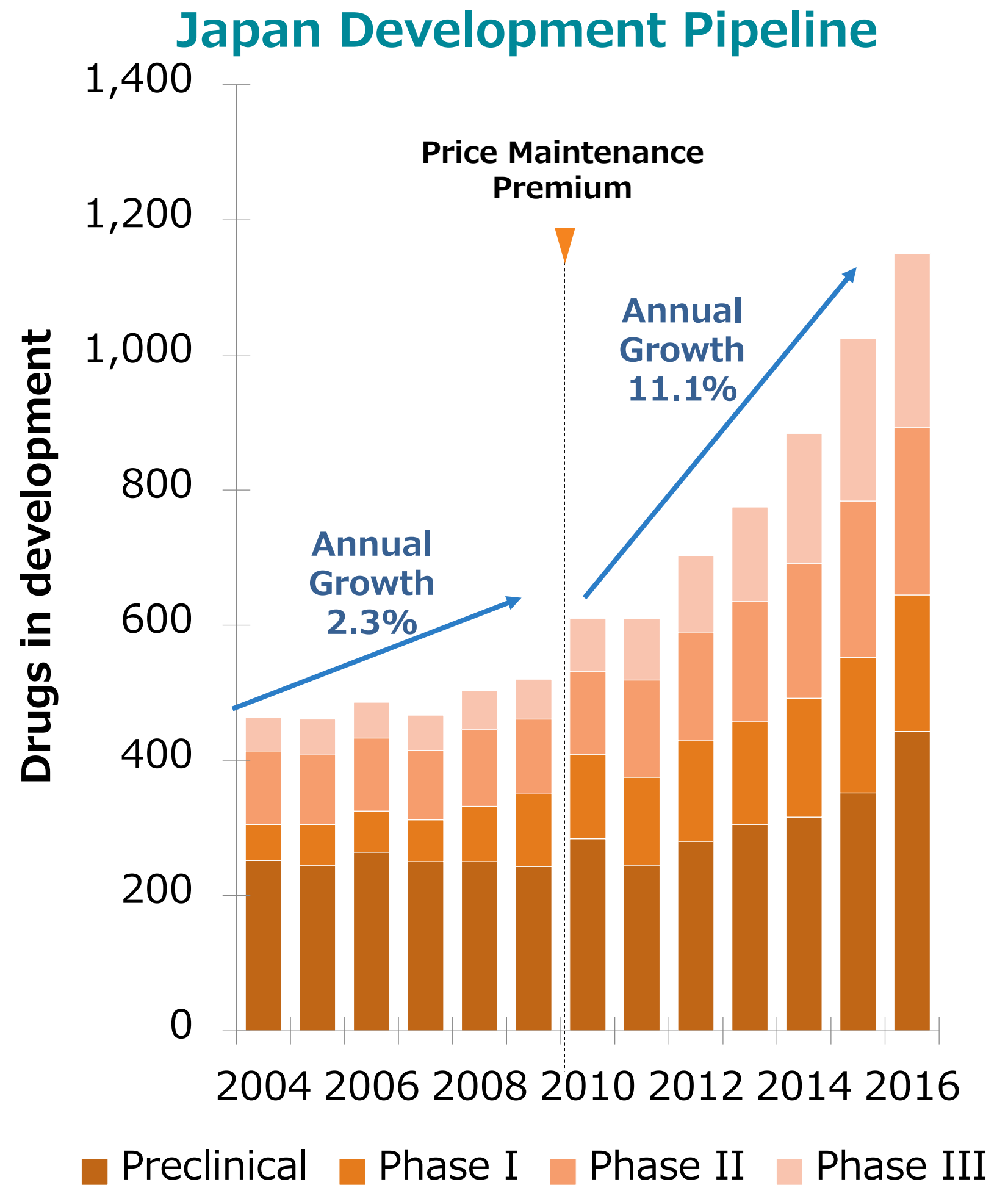
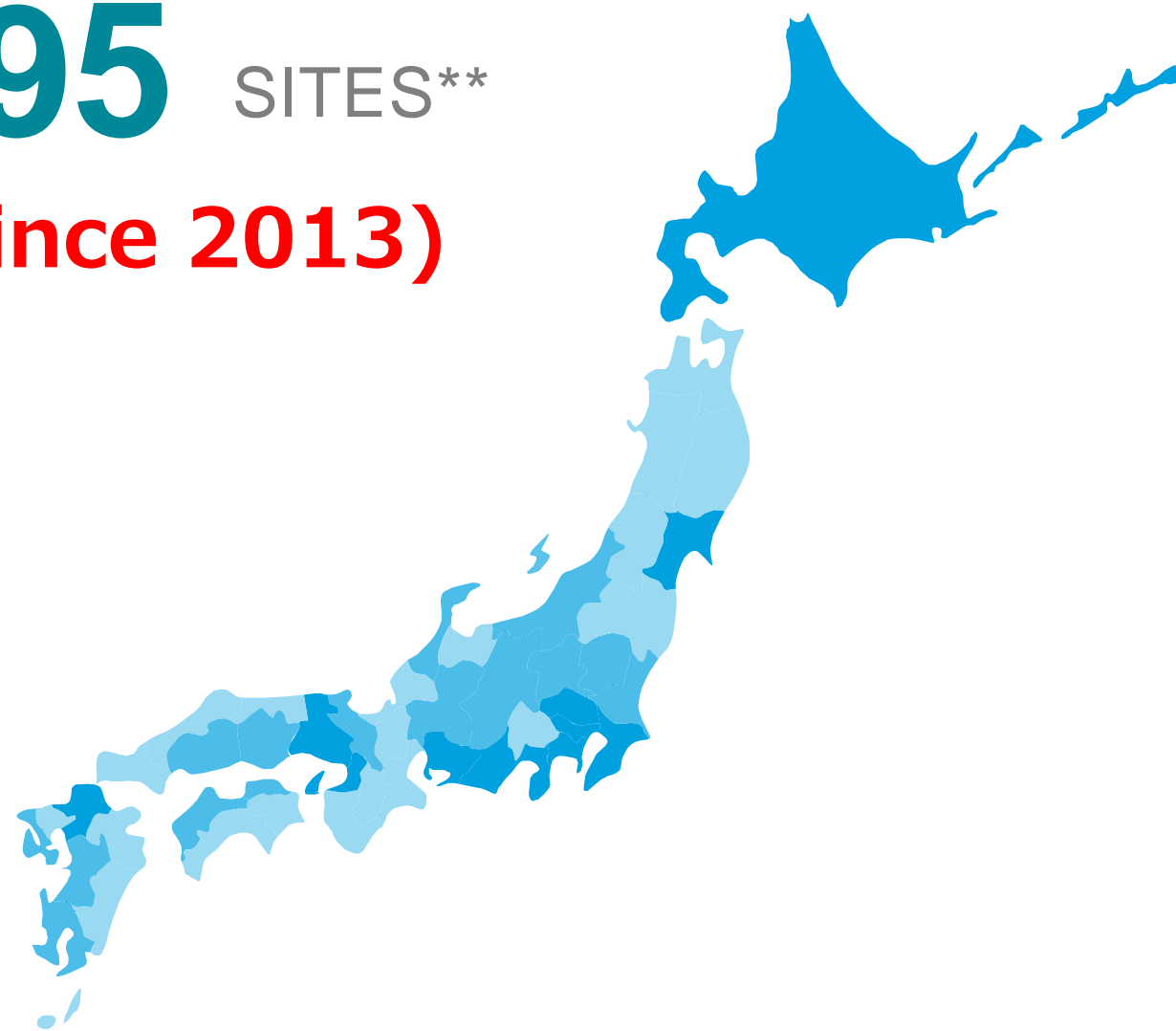
Number of EFPIA & PhRMA
sponsored clinical trials 2015

825 CLINICAL TRIALS*

(+21% since 2013)

18,095 SITES**

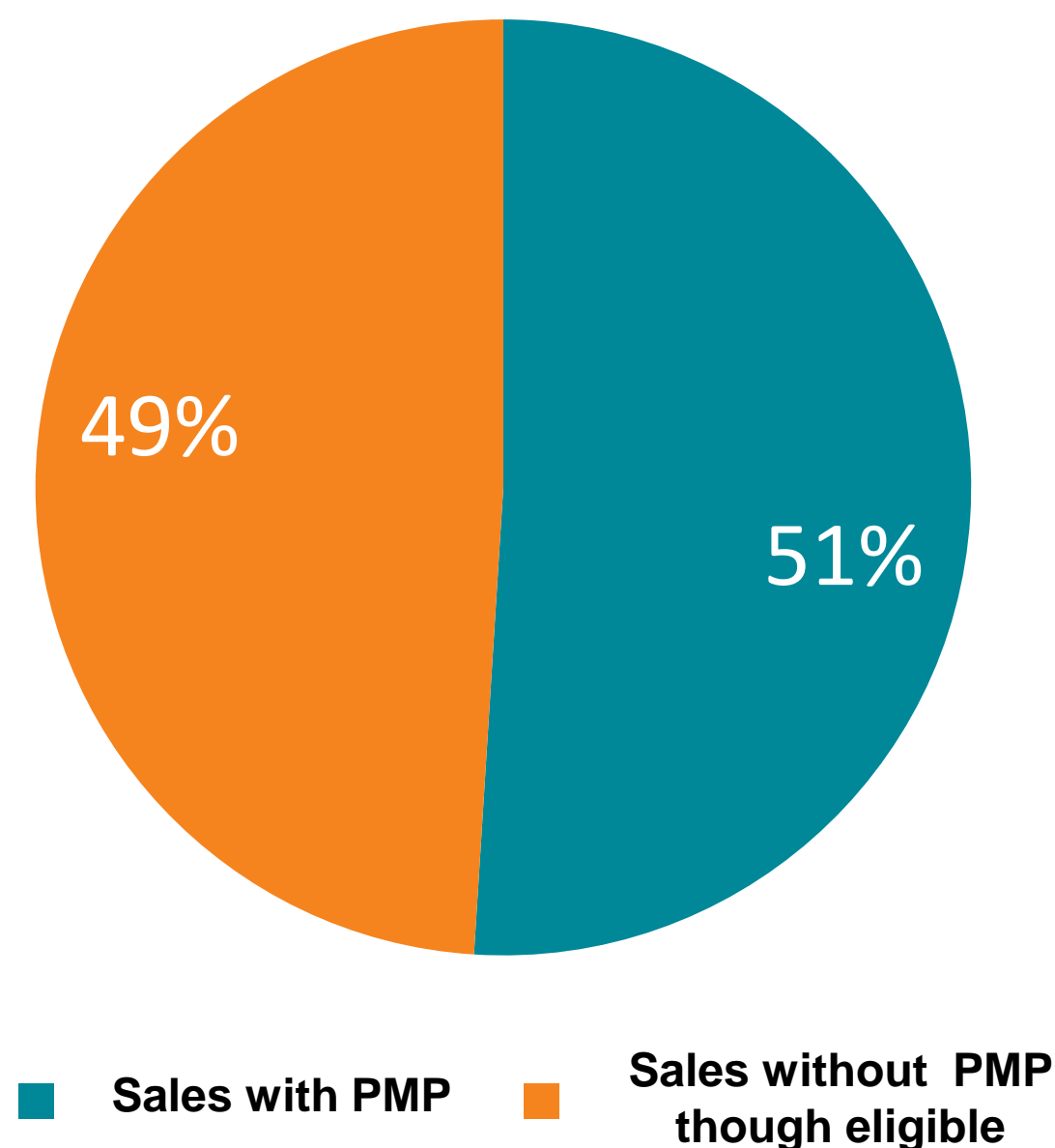
(+55% since 2013)



Price Maintenance Premium rewards innovation, not foreign companies!

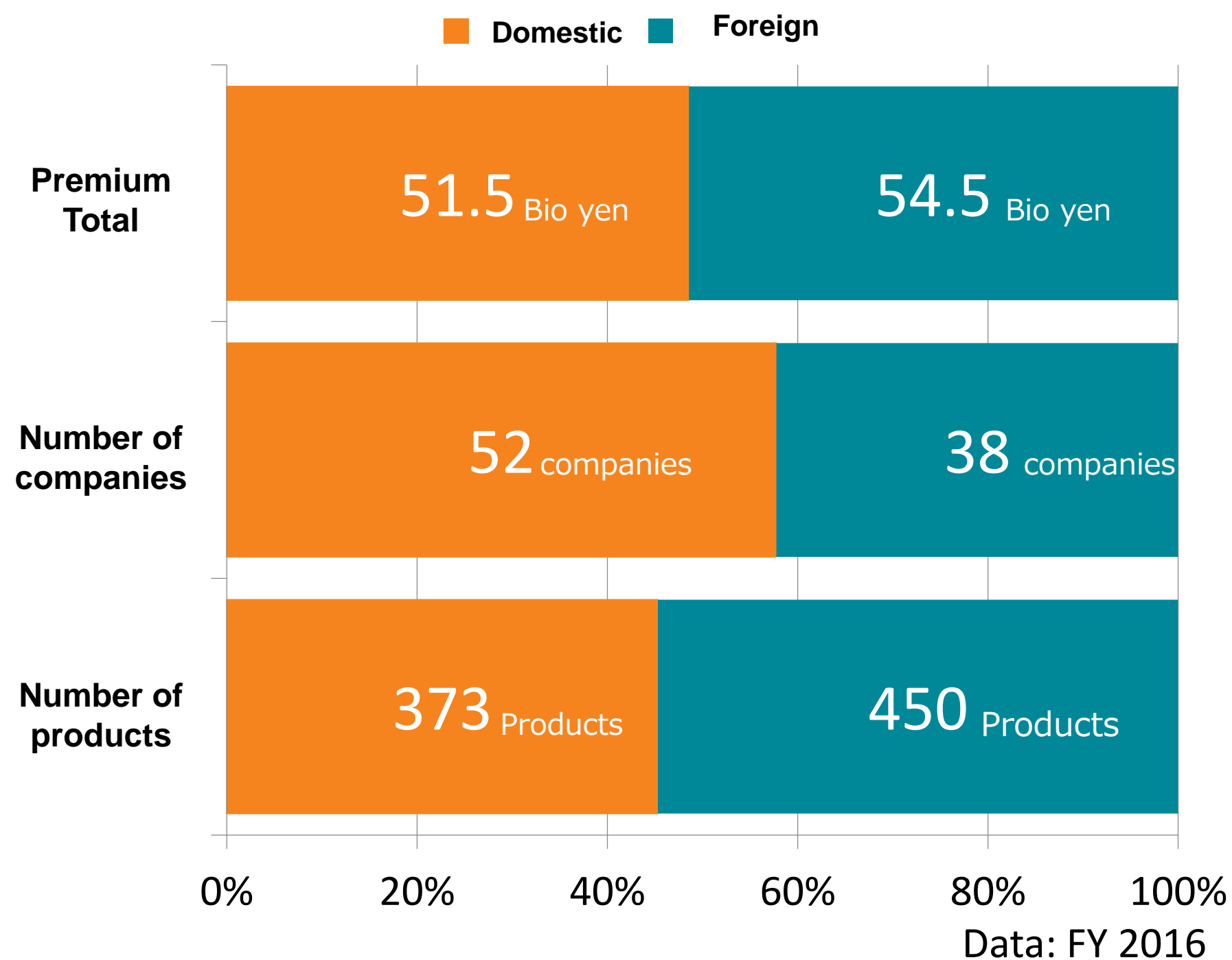
And not all innovations receive the premium

- By sales, only half of products eligible for PMP receive the premium



Data: 2016

- PMP is awarded to both domestic and foreign companies



RISFAX (MHLW reports to LDP Healthcare committee)

EFPIA is willing to make a contribution to sustainability of healthcare system... IF the price maintenance premium is continued

EFPIA acknowledges that sustainability of universal healthcare coverage means that healthcare services need to be managed more efficiently across the entire value chain to control costs

EFPIA is willing to support the proposal for an immediate price revision following market expansion by additional indications (provided that it is restricted to cases where the product has huge sales and where the additional indication(s) increases sales significantly)

EFPIA is willing to support annual re-pricing (provided that adjustment is limited to LLP and Gx discounting from the NHI price beyond a certain percentage)

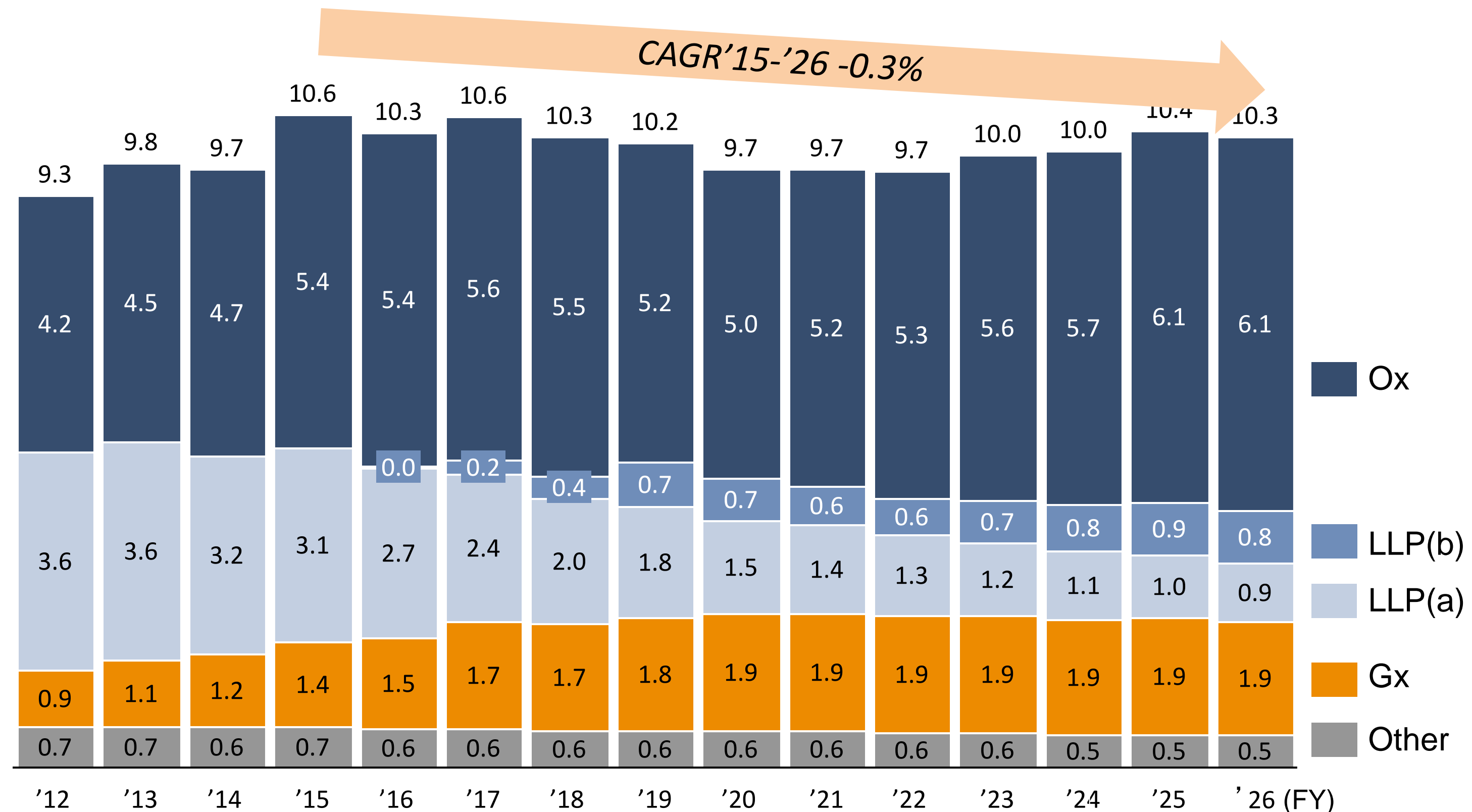
EFPIA is open to discussing alternatives to the cost-plus price-setting method

EFPIA is open to alternative measures of the US reference price

Even the “high” case is for a broadly flat pharmaceutical market

High case assumes: (i) expansion of price maintenance premium to all eligible products; (ii) 5 more new drugs developed than in base or low cases; (iii) later achievement of 80% Gx rate; (iv) annual price revision for LLP and Gx with large deviation; and (v) launch of highly innovative drugs ¥500 Bn / year at peak time

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



Source: IMSBase JPM

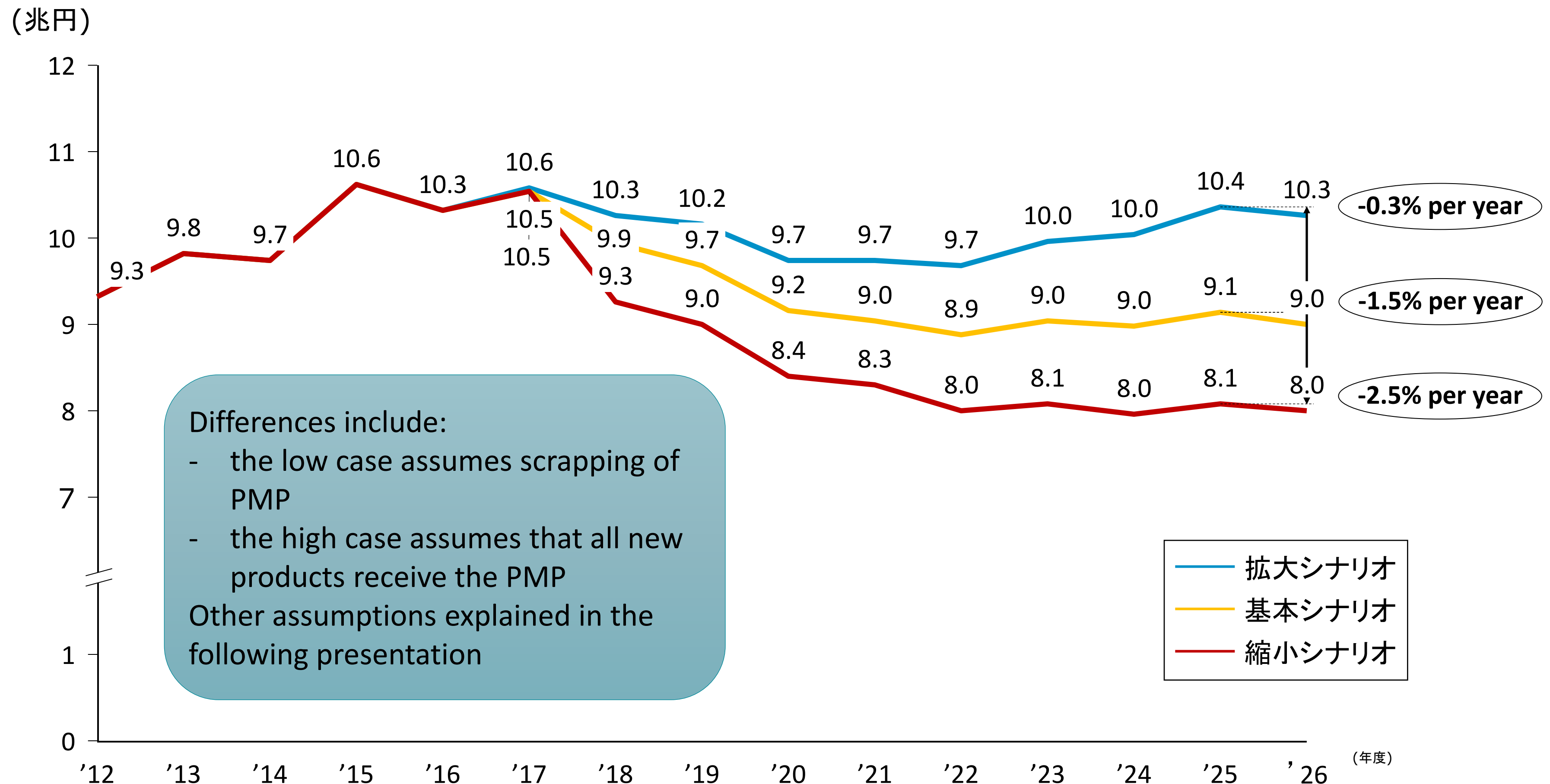
*1 Ox: Original products, LLP (a): generic drugs launched before 2016, LLP (b): generic drugs launched after 2017, or planned to be launched, Gx: Generic products

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All three scenarios in the IMS analysis conclude that the drug market will be flat or declining over the next decade

市場の成長 (シナリオ別)



Source: IMSBase JPM

Lessons from the drug market forecasts

The drug market in Japan will be flat or slightly declining over the next decade

- The analysis shows that even in the optimistic high case, the drug market in Japan will be declining -0.3% p.a. during the coming 10 years
- Average annual growth is forecast to be -1.5% in the base case, and for the low case -2.5%

Japan likely to be the lowest growing market among major markets

- The EFPIA-J and QuintilesIMS forecast only focused on Japan and no direct comparison between this analysis and other markets can be made.
- However other analysis of other developed markets suggest they are likely to grow (+2% to +5% p.a. during the period 2016-21)
- With a declining market in Japan and growth in the rest of the world there is a risk Japan will be deprioritized for global investment and the drug lag might worsen again

The analysis clearly suggests: Japan can continue to reward innovation AND make budget savings

- The drug budget is already set to be well controlled, primarily as a result of existing measures and the higher Gx target
- Based on the EFPIA-QuintilesIMS simulation it is clear the PMP can be maintained while achieving the government's desired control of the drug budget



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THANK YOU