European Federation of Pharmaceutical Industries and Associations

JAPAN: Continuing the success

* October 6, 2015





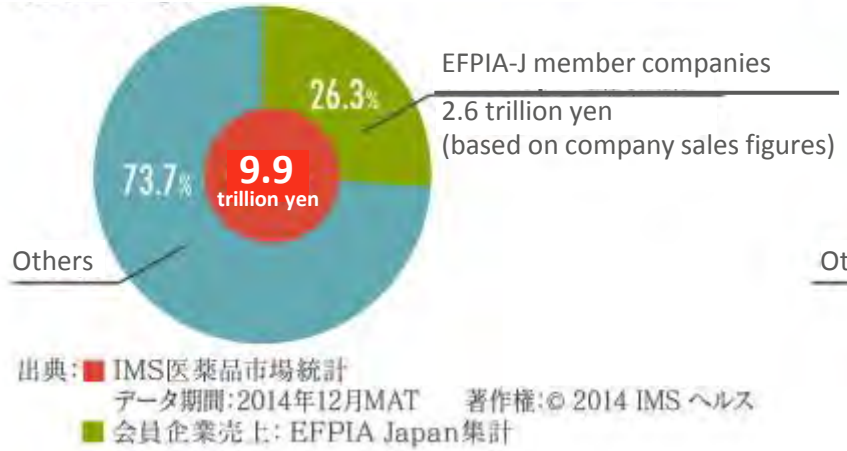

EFPIA Japan Days

Dr Carsten Brunn

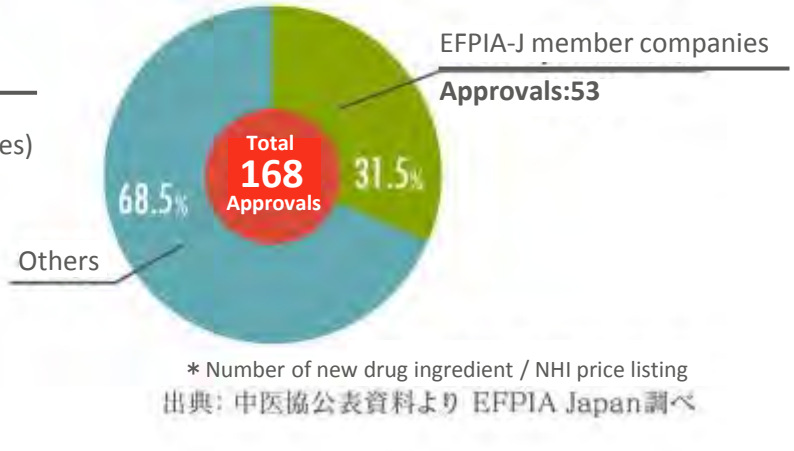
Chairman, EFPIA Japan

EFPIA Japan - development and marketing of innovative new drugs

EFPIA-J member companies Sales in Japan （2014）

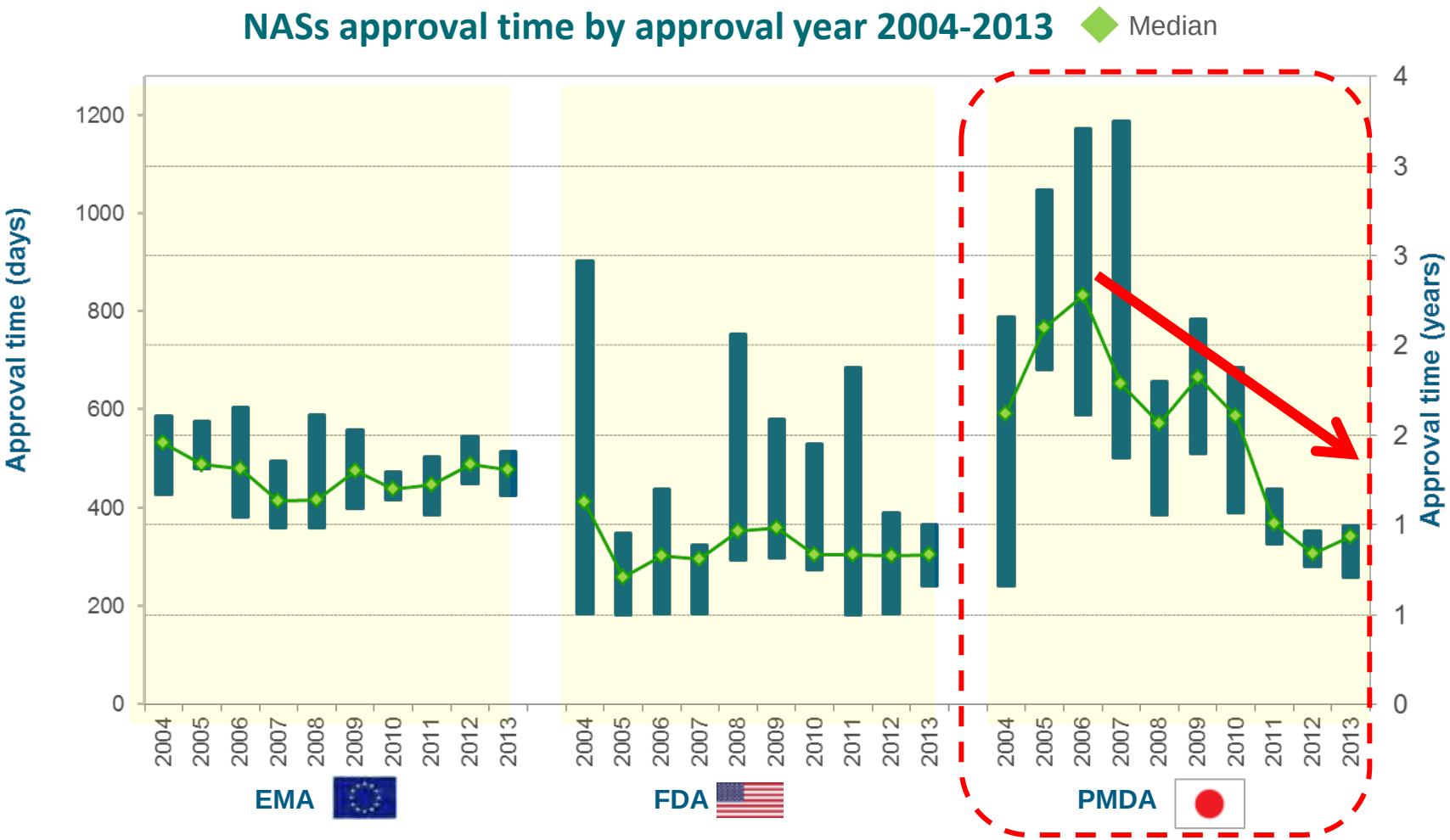


New drug approvals＊ （2012-14）



Abbott Japan Co., Ltd.
Actelion Pharmaceuticals Japan Ltd.
AstraZeneca K.K.
Baxalta Japan Limited
Bayer Yakuhin, Ltd.
Bracco-Eisai Co., Ltd.
CHUGAI PHARMACEUTICAL CO., LTD.
CSL Behring K.K.
Ferring Pharmaceuticals Co., Ltd.
GALDERMA K.K.
GE Healthcare Japan Corporation
GlaxoSmithKline K.K.
Guerbet Japan KK
Ipsen Pharma
JANSSEN PHARMACEUTICAL K.K.
LEO Pharma K.K.
Lundbeck Japan K.K.
Merck Serono Co., Ltd.
NIHON SERVIER COMPANY LIMITED
Nippon Boehringer Ingelheim Co., Ltd.
Novartis Pharma K.K.
Novo Nordisk Pharma Ltd.
Sanofi K.K.
Shire Japan KK
UCB Japan Co. Ltd.

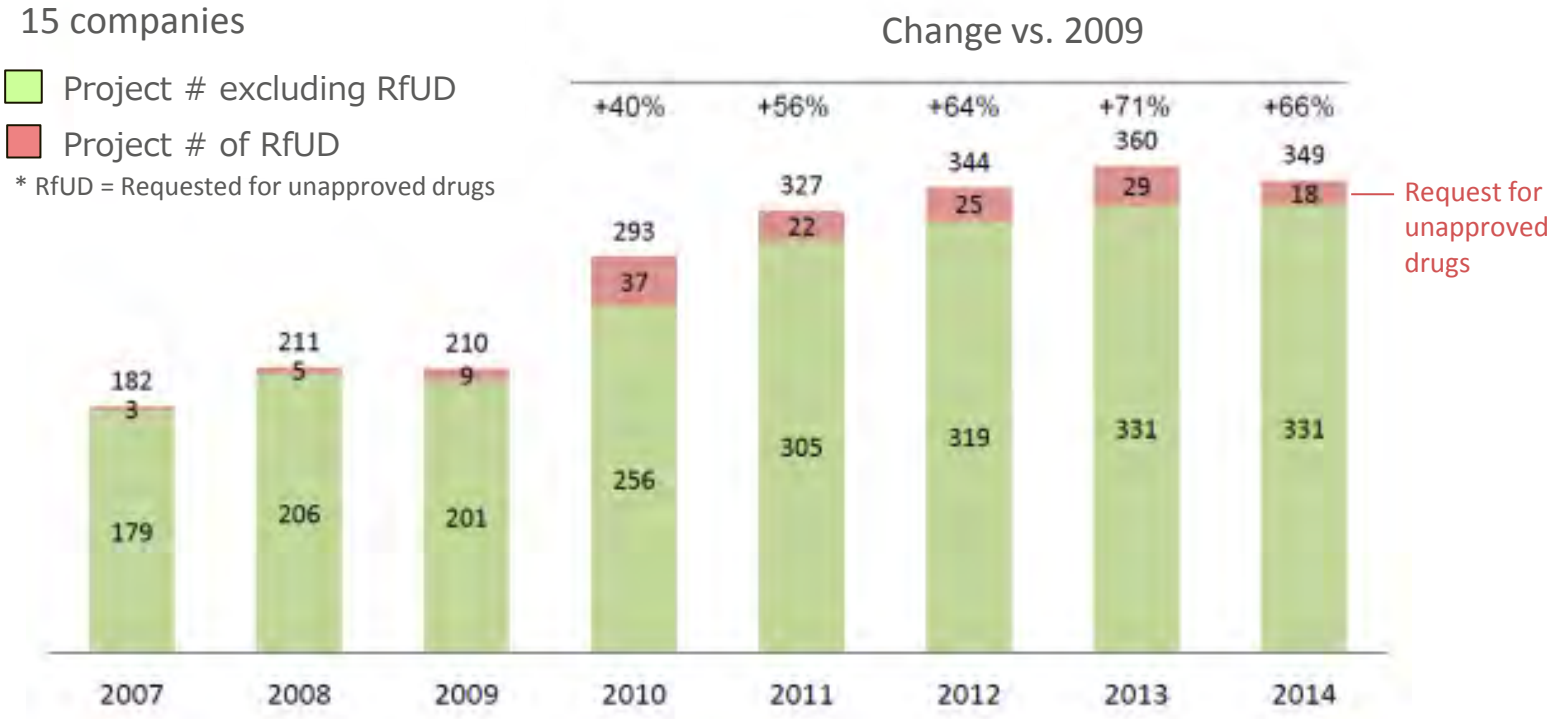
Regulatory review periods have halved



Source: CIRS (Centre for Innovation in Regulatory Science) in the UK

The Innovation Premium has worked!

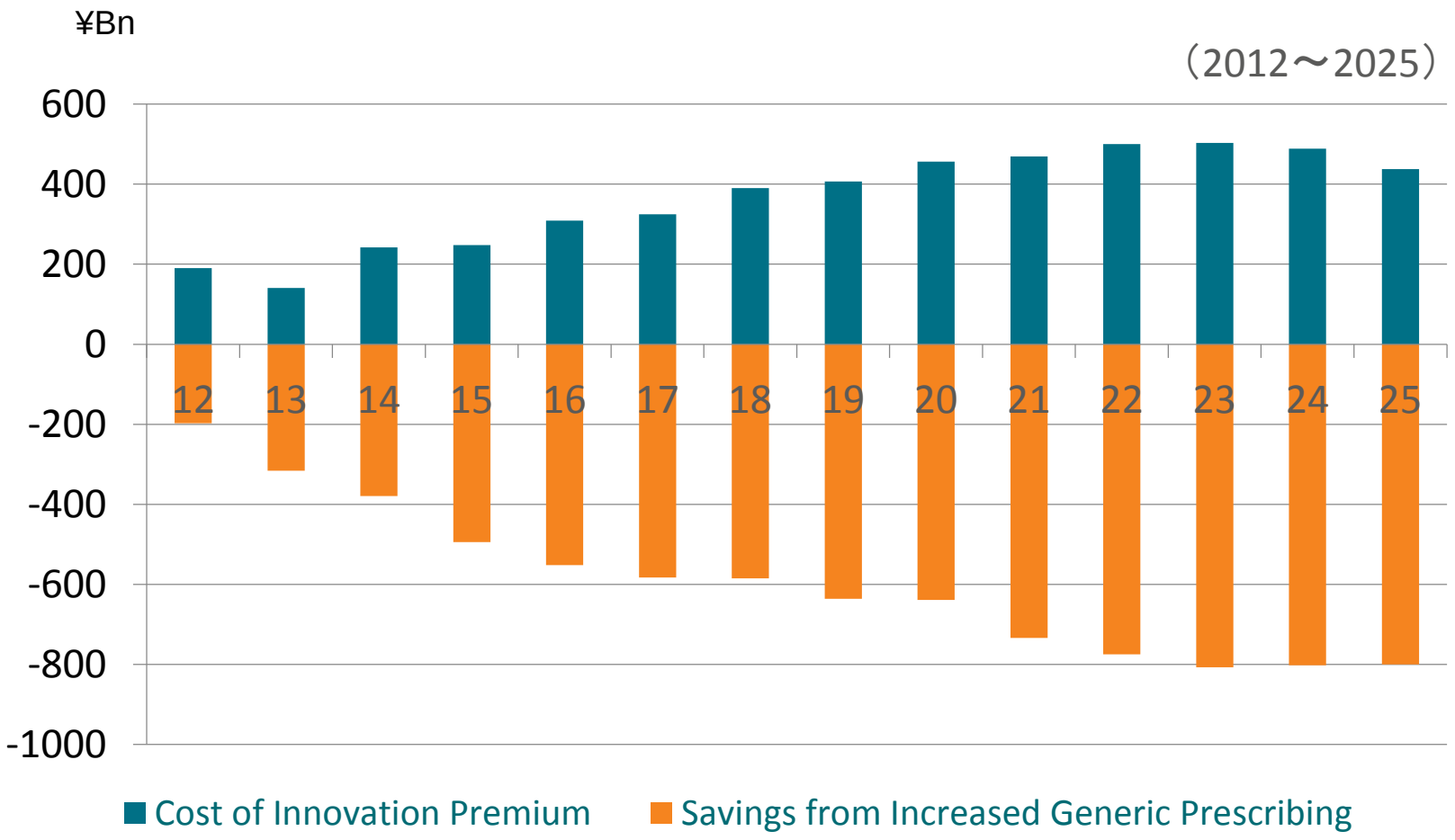
The number of drug development projects in Japan is up sharply since the launch of the Innovation Premium in 2010



† Some projects were initiated prior to request for unapproved drugs.

Source: EFPIA Japan survey (data from 15 companies)

Savings from generics have more than paid for the cost of the Innovation Premium

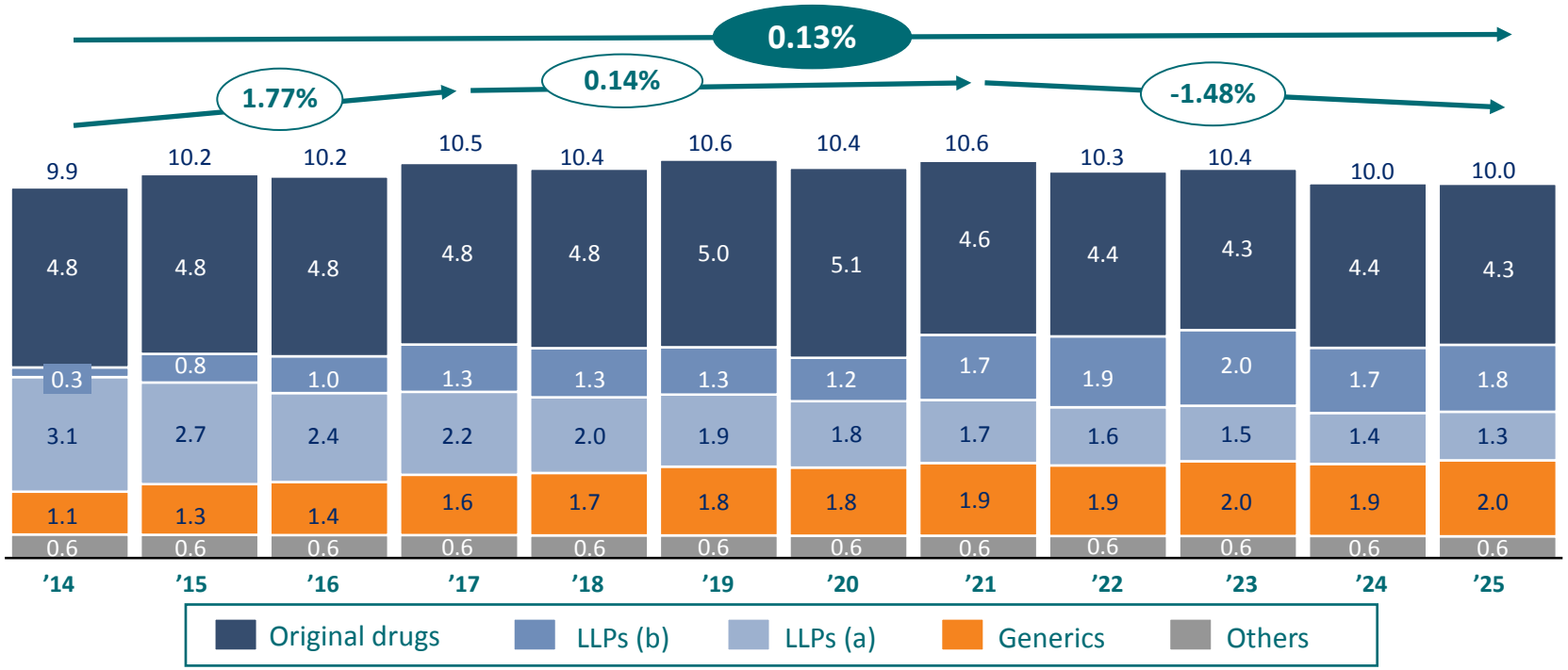


Source: EFPIA/IMS Simulation Study, 2014

Continuation of current policies: Costs well controlled, market broadly flat

Forecast market growth by segment (¥Tn) *1,2

Innovation premium scheme and biennial pricing continue



*1 LLPs (a) are long-listed products (LLPs) whose first generic alternative was launched before 2013. LLPs (b) are the other LLPs, whose first generic competitor is launched after 2013.

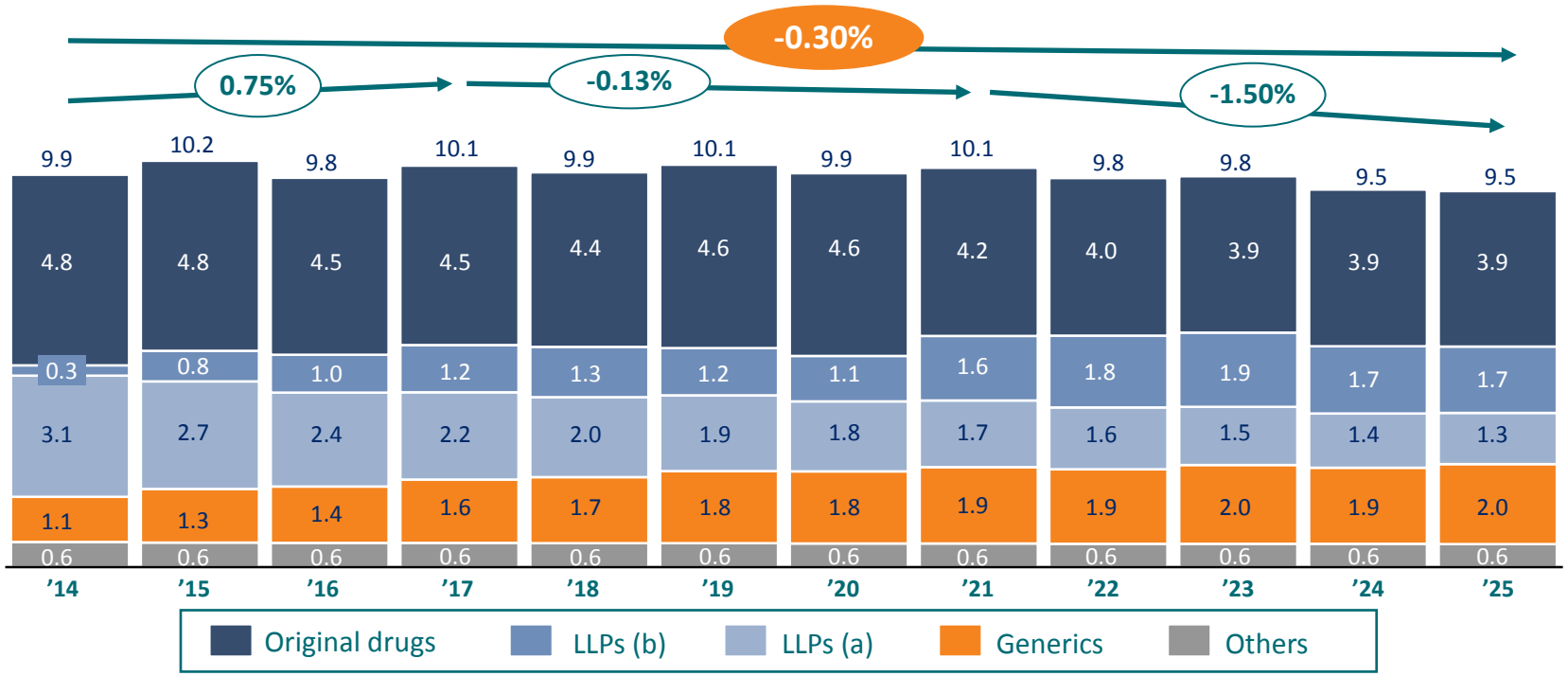
*2 Sales are calculated assuming that the 5% consumption tax rate that existed on 1 January 2014 continues throughout the period. This is in order to look at the underlying growth in the market, stripping out the consumption tax effect.

Source: IMS Consulting Group

No innovation premium?
The pharmaceutical market will decline

Forecast market growth by segment (¥Tn) *1,2

Innovation premium scheme discontinued; biennial pricing continues



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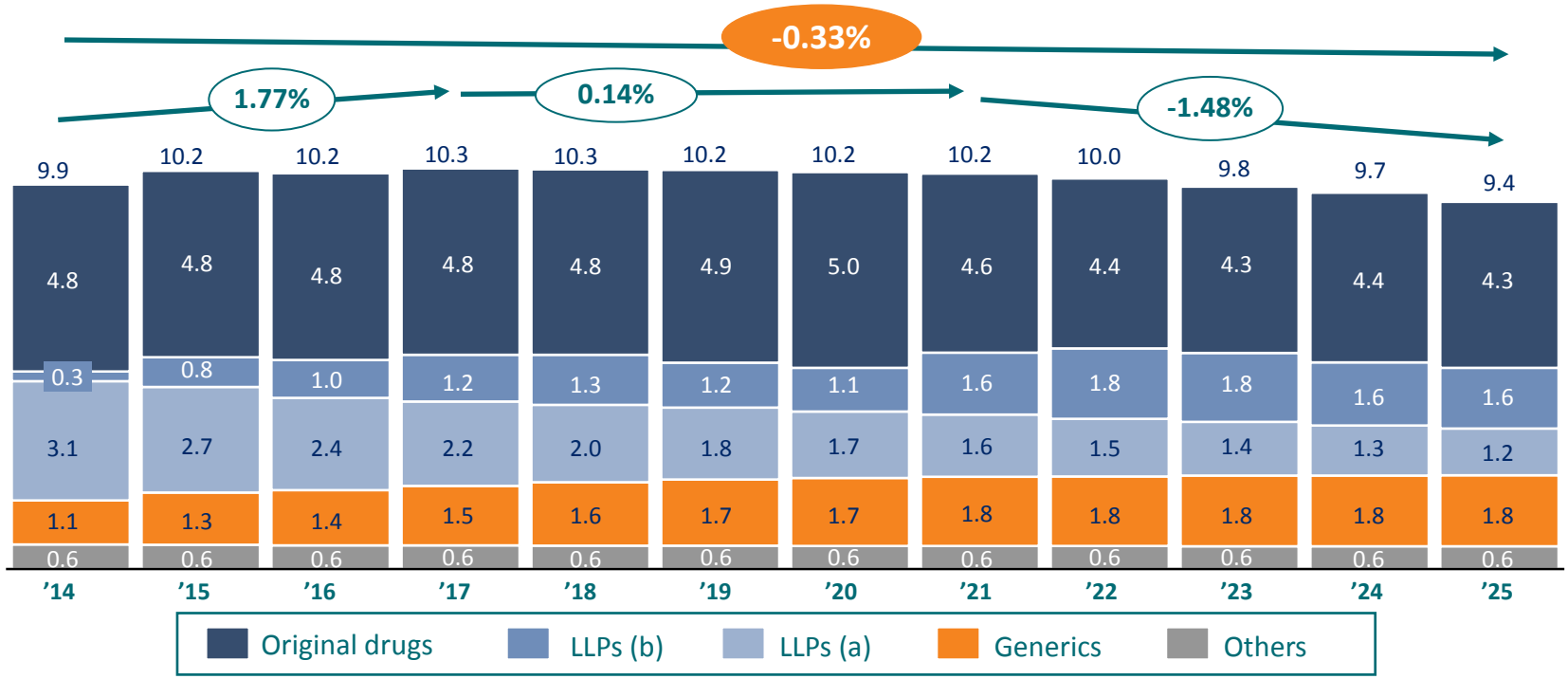
Source: IMS Consulting Group

Annual repricing?
This too would shrink the total market

Forecast market growth by segment (¥Tn) *1,2

Innovation premium scheme continues but annual pricing from 2016



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Source: IMS Consulting Group

Maintaining a pro-innovation pricing environment

The innovation premium needs to be continued in its current form beyond 2016

- Predictable pricing that rewards innovation has attracted new investment to Japan
- Abolition or limitation of the innovation premium would lead to negative growth for the market as a whole, with the majority of the damage done to the innovative sector. This would contradict Japan's pro-innovation policy stance

Annual price revisions must be avoided

- A simple adjustment (existing prices x 110/108) to account for the new consumption tax rate in April 2017 is sufficient. There is no logical connection between the planned tax increase and a broader price adjustment.
- Annual price revisions would lead to negative growth for the market as a whole. This too would contradict Japan's pro-innovation policy stance

Health Technology Assessment (HTA)

"The process that uses evidence to evaluate the clinical efficacy, cost-effectiveness and broader impact of a health technology on patients and the health care system"

International Society for Pharmacoeconomics and Outcomes Research (ISPOR)

Barrier to patient access

- "Pancreatic cancer patients to pay $15,000 or miss out" – Herald Sun (Australia)
- "Patients protest after kidney drugs rejected [by NICE]" – The Guardian (UK)
- Alzheimer's drugs [access] court challenge – BBC News (UK)

HTA in Japan – Current Status

- Leaning towards using cost-effectiveness analysis (CEA) HTA for re-pricing of existing products

- Selection criteria of products undecided, but seems agreement that significant budget impact and a high unit price (daily treatment cost) should be key criteria

Remaining questions:

- How exactly would the product in question be re-priced?
- How to incorporate HTA into the current pricing system? Would "HTA re-pricing" piggyback on the existing re-pricings, e.g. "market expansion re-pricing", or work as a stand-alone re-pricing?

HTA in Japan – EFPIA's view

Collaboration

- Involve all stakeholders in meaningful discussions at all stages of the process

Limited introduction

- Set priorities for the initial, trial period of HTA

Focus on outcomes

- Focus on achieving better outcomes, not solely on costs, and combine clinical trial data with other data sources such as real world evidence

No impact on access

- Ensure no negative impact on patient access or physicians' freedom to prescribe

Minimize burden

- Reward innovation and minimize the burden for both government and industry

Japan: continuing the success

Continue the innovation premium

Avoid annual repricing

Ensure that HTA is not a barrier to patient access