PhRMA
Annual Press Conference

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PhRMA

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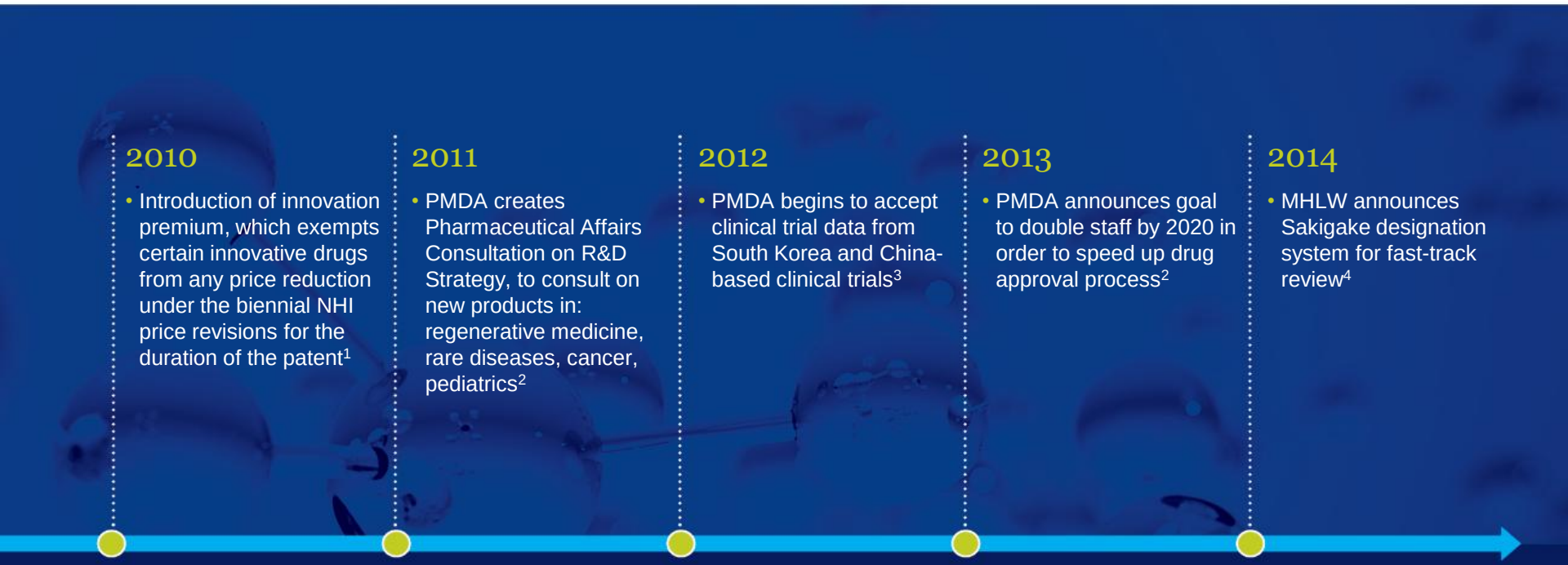
RESEARCH • PROGRESS • HOPE

Japanese Policy Changes Have Fostered Patients' Access to New Medicines

- Thanks to the transformation of the PMDA, pricing stability, and predictability, innovative medicines have become accessible to Japanese patients much more quickly
- Pro-innovation policies such as price maintenance premium and sakigake system by the Japanese government have yielded positive results
- Also, we have seen an unprecedented wave of innovative medicines that allow doctors to treat devastating diseases like cancer and hepatitis C

Improved conditions drive innovation



2010

- Introduction of innovation premium, which exempts certain innovative drugs from any price reduction under the biennial NHI price revisions for the duration of the patent[1]

2011

- PMDA creates Pharmaceutical Affairs Consultation on R&D Strategy, to consult on new products in: regenerative medicine, rare diseases, cancer, pediatrics[2]

2012

- PMDA begins to accept clinical trial data from South Korea and China-based clinical trials[3]

2013

- PMDA announces goal to double staff by 2020 in order to speed up drug approval process[2]

2014

- MHLW announces Sakigake designation system for fast-track review[4]

Observed Improvements

In 2014, the submission gap was
21 months shorter
than it was in 2010[7]

From 2009 to 2014 the number of approved innovative therapies in Japan
increased by 93%[6]

Number of medicines in development increased from
619 in 2009 to over 1,200 in 2015[5]

Source: Health Advances analysis; [1]Deloitte 2015 Life sciences outlook Japan; [2]PMDA 2012 Current topics of pharmaceutical regulatory affairs in Japan; [3]PPD 2013 Conducting clinical trials in Japan: A CRO perspective; [4]MHLW June 2014 Strategy of Sakigake; [5]PharmaProjects (accessed April 2016); [6]PMDA 2009-2014 Products Approved; [7]CIRS 2015 New drug approvals in ICD Countries 2005-2014.

Innovative Medicines Have Increased Survival Rates in Japan

Cancer

New therapies have contributed to significant declines in cancer death rates in Japan since its peak in 1995.

Today,
3 out of 5 people
diagnosed with cancer
in Japan survive
at least 5 years[1]

Percent Decline in Cancer Mortality Rates Since 1995

1995 to 2013 – All Cancers[2]

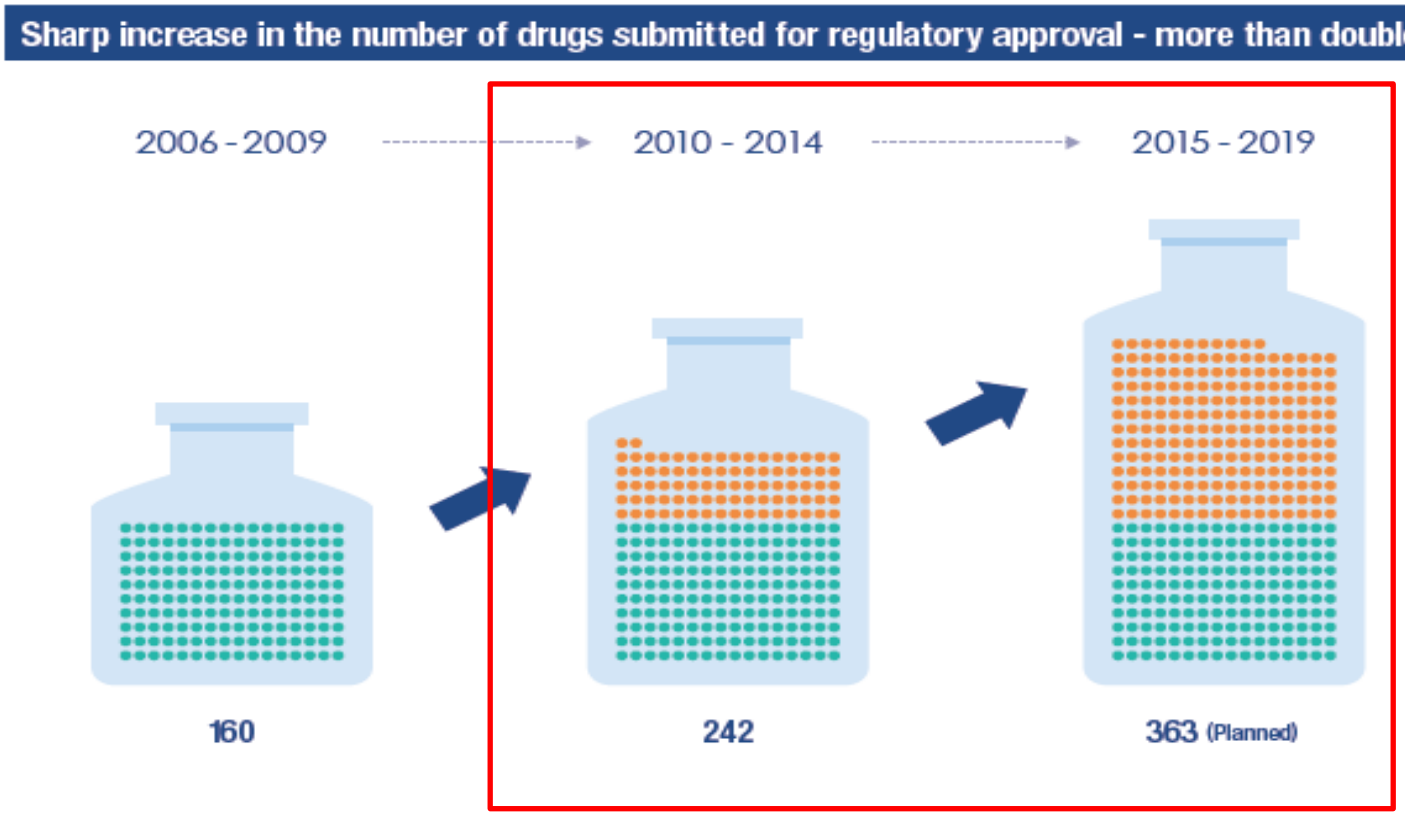
USA	-24%
Japan	-20%
Germany	-20%
United Kingdom	-20%

1995 to 2013 – Various Cancers in Japan[2]

Colon	-12%
Stomach	-45%
Lung	-10%
Lymphomas	-11%
Leukemia	-22%

Source: Health Advances analysis; [1]FPCR 2014 Cancer Statistics in Japan; [2]WHO Mortality Database (accessed February 2016).

Full Benefit Still in Front of Us in Japan



*1 27 companies responded on new drugs that have been submitted or will be submitted for regulatory approval in Japan between 2006-2019 (Excludes drugs developed at the request of MHLW)

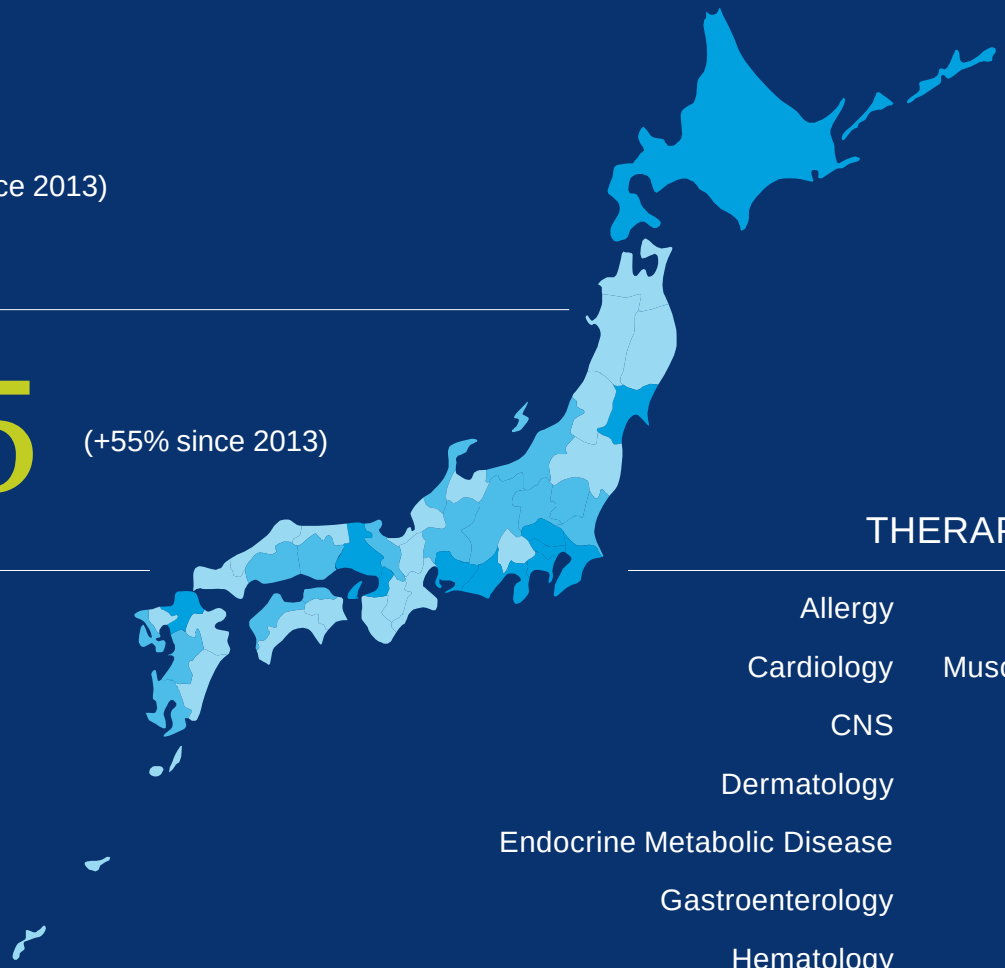
Continued increase in investment in clinical development across Japan

825 (+21% since 2013)

CLINICAL TRIALS*

18,095 (+55% since 2013)

SITES**



16+

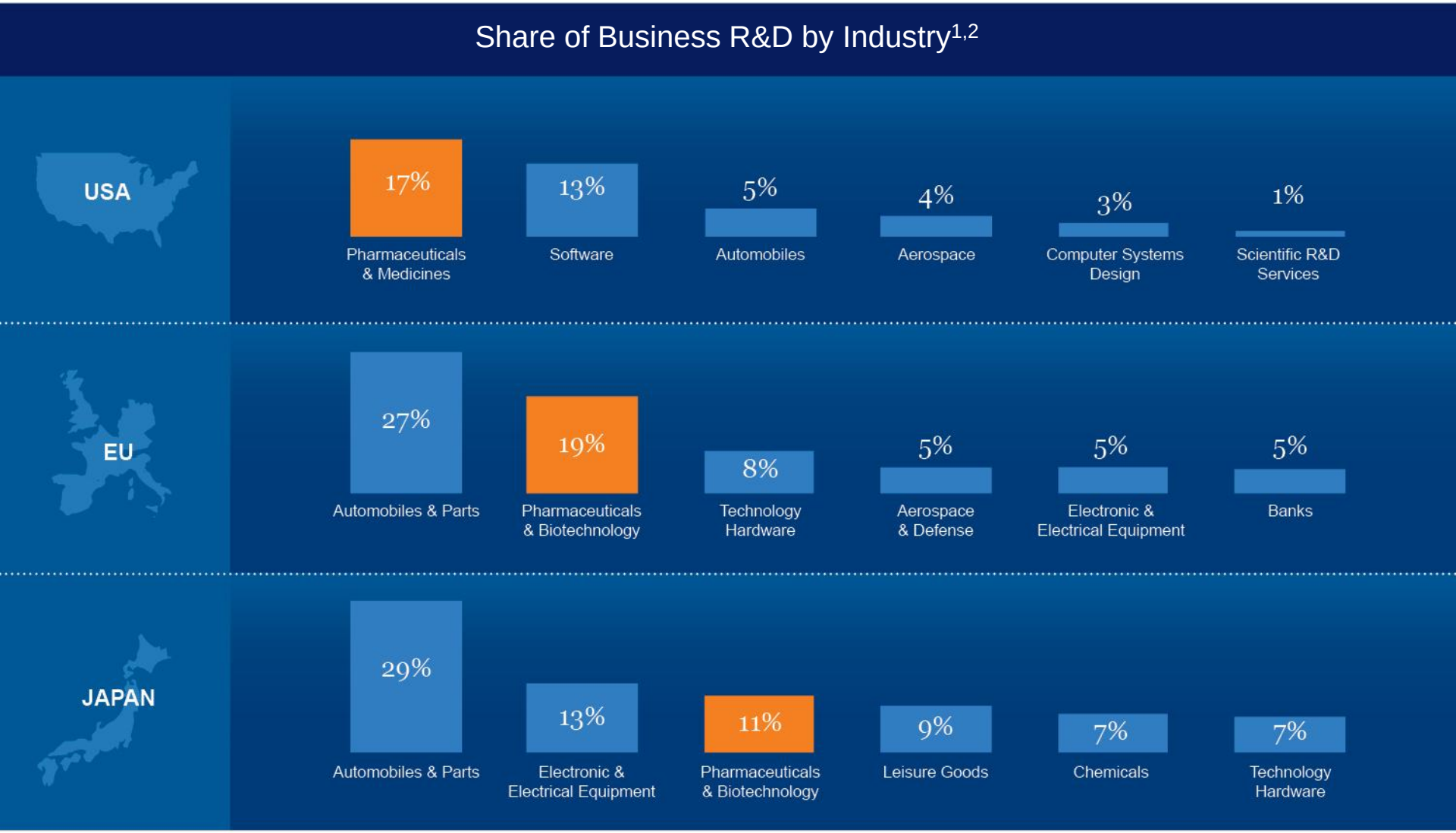
THERAPEUTIC AREAS

- Allergy
- Cardiology
- CNS
- Dermatology
- Endocrine Metabolic Disease
- Gastroenterology
- Hematology
- Immunology
- Infectious Disease
- Musculoskeletal Disease
- Oncology
- Ophthalmology
- Respiratory Disease
- Urology
- Rare Diseases
- Others

Source: www.clinicaltrials.gov (2015 data)

*Figures do not include post marketing surveillance **Individual sites participating in multiple trials are counted multiple times

The Biopharmaceutical Sector in Japan Has the Potential to Become the Largest Investor



Note: The remaining share of business R&D spending is conducted by other industries, including subsectors of the machinery sector, the electrical equipment sector, and the professional, scientific, and technical services sector.
Source: [1]PhRMA analysis of National Science Foundation, National Center for Science and Engineering Statistics, data. Funds spent for business R&D performed in the United States, by source of funds and selected industry: 2013; [2]European Commission, 2016, The 2016 EU industrial R&D investment scoreboard.

The Aging Population in Japan Is Straining the Japanese Health Care System

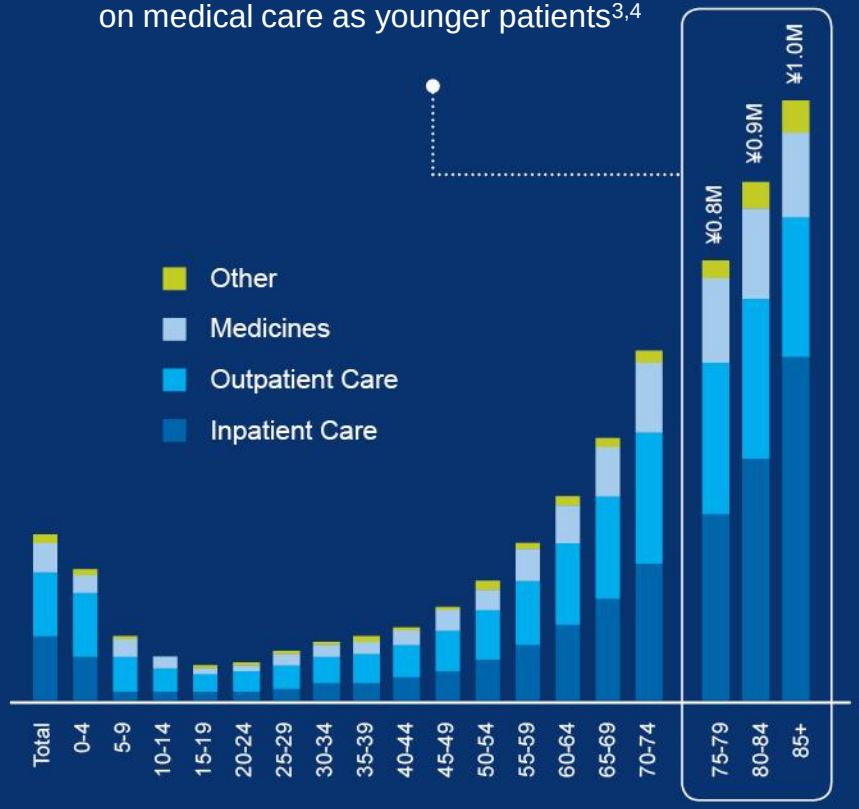
The elderly population is expected to make up over

20% of Japan's population by 2040[1]

Elderly patients spend per capita

4 times the amount of money

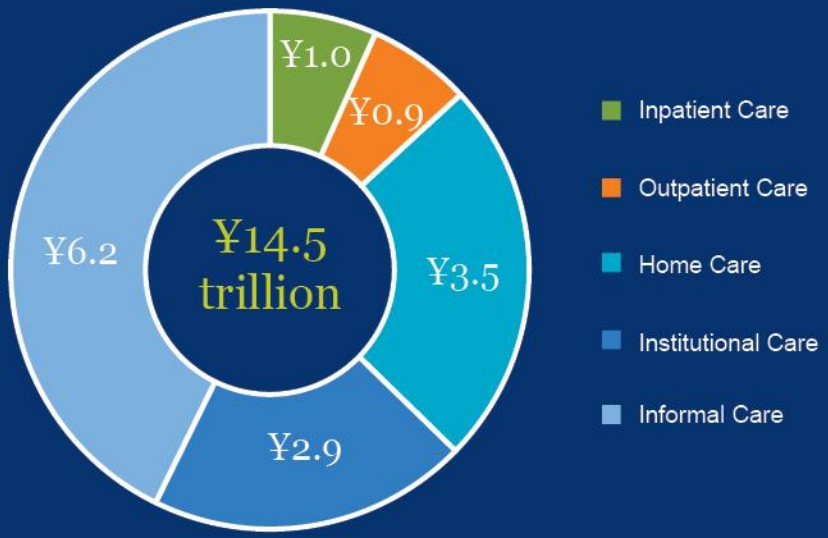
on medical care as younger patients[3,4]



Source: [1]US Census Bureau International Database (accessed April 2016); [2]Ministry of Health, Labour and Welfare, 2013, Health Statistics in Japan; [3]Ministry of Health, Labour and Welfare, 2015, Annual health, labour and welfare report; [4]Ministry of Health, Labour and Welfare, 2012, Overview of medical service regime in Japan.

The Needs to Continue Investing in Innovation To Develop New Medicines

In 2014, the societal cost of dementia was ¥14.5 trillion,
nearly 3% of Japan's GDP[1]



100,000

The number of people quitting their jobs each year to care for sick family members[1]

~50%

The percentage of the societal care cost for dementia that is borne by families[1]

30 months

The amount of time spent in nursing home care per patient that could be delayed if currently available medicines were used for at least 9 months[2]

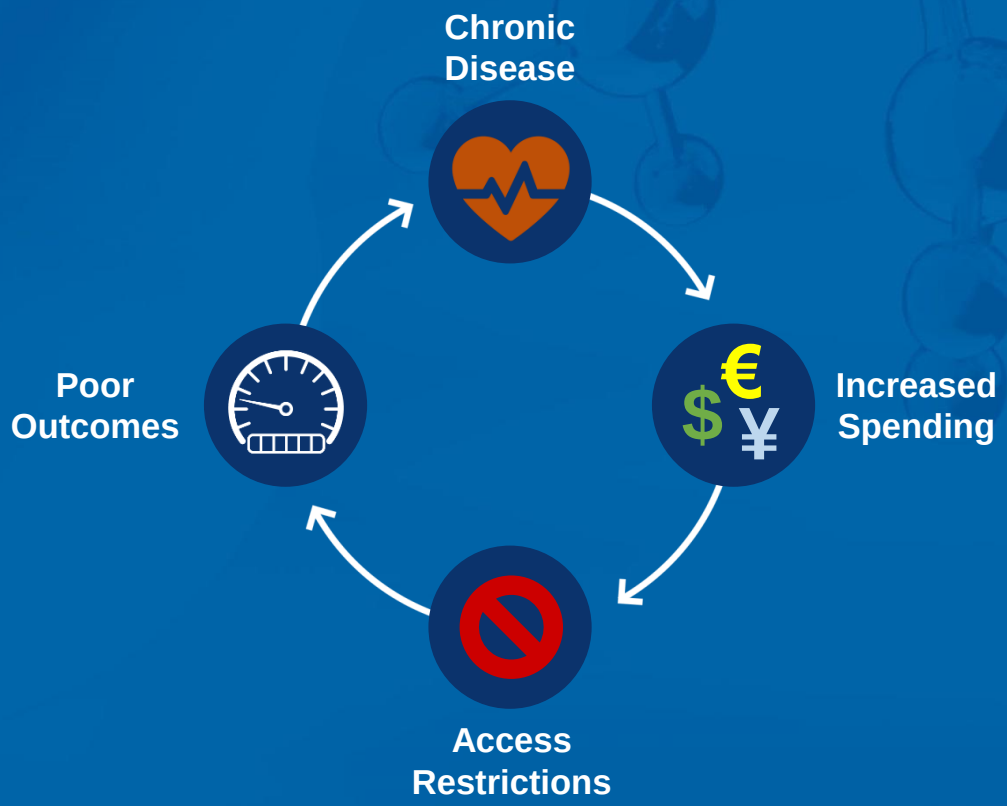
By 2060, the projected societal costs of dementia are estimated to be

¥24.3 trillion

Source: Health Advances analysis; [1]Ministry of Health, Labor and Welfare 2014 study as cited in October 2015 International Conference on Cognitive Decline and its Economic Consequences; [2]Provenzano 2008 Delays in nursing home placement for patients with Alzheimer's Disease associated with treatment with donepezil may have health care cost-saving implications Value in Health.

Vastly Different Health Care Systems with Some Common Challenges

Innovation Medicines Can Be Part of the Solution, but…



Today's medicines are dramatically different from the medicines of a decade ago, but the way countries plan for, regulate, and fund innovation has not kept pace

Uncertainty and Unpredictability in the Japanese Marketplace

Japan Biopharma Innovation

Innovation is harder and more costly

- Per-patient clinical trial costs in Japan are two to six times higher than anywhere else in the world[1]

Investments in innovation are increasingly risky given the unpredictability of the Japanese market

- The innovation premium has not yet been made permanent[2]
- Potential introduction of annual price revisions will make R&D investment and drug launch in Japan less attractive[3]
- The stagnant Japanese economy is a risk to future investments in health care

Challenges exist impeding patient access

- "Optimal Use Guidelines" are introducing uncertainty in the new product adoption process
- HTA programs that impose cost-effectiveness at the point of listing new drugs threaten to undo progress made minimizing the submission gap[4]

Source: Health Advances analysis; [1]Chiu 2013 Conducting clinical trials in Japan: A CRO Perspective PPD; [2]IHS 2015 Japan's comprehensive strategy for pharmaceutical sector calls for innovation and M&A; [3]PhRMA 2016 Views and Requests on Drug Price Revision; [4]EFPIA 2015 HTA Application in select markets and implications for Japan.

Investment in Japan Would Become Even More Risky

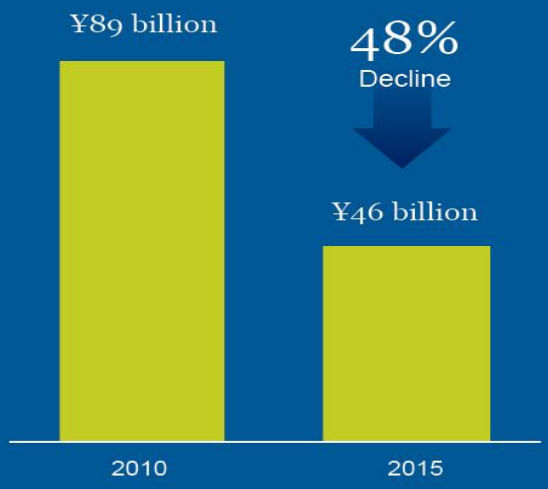
As costs to develop a medicine has increased by 1/3rd,
Average peak sales per medicine have been halved since 2010

Since 2010, the average cost of developing a novel therapeutic has

INCREASED BY 33%...

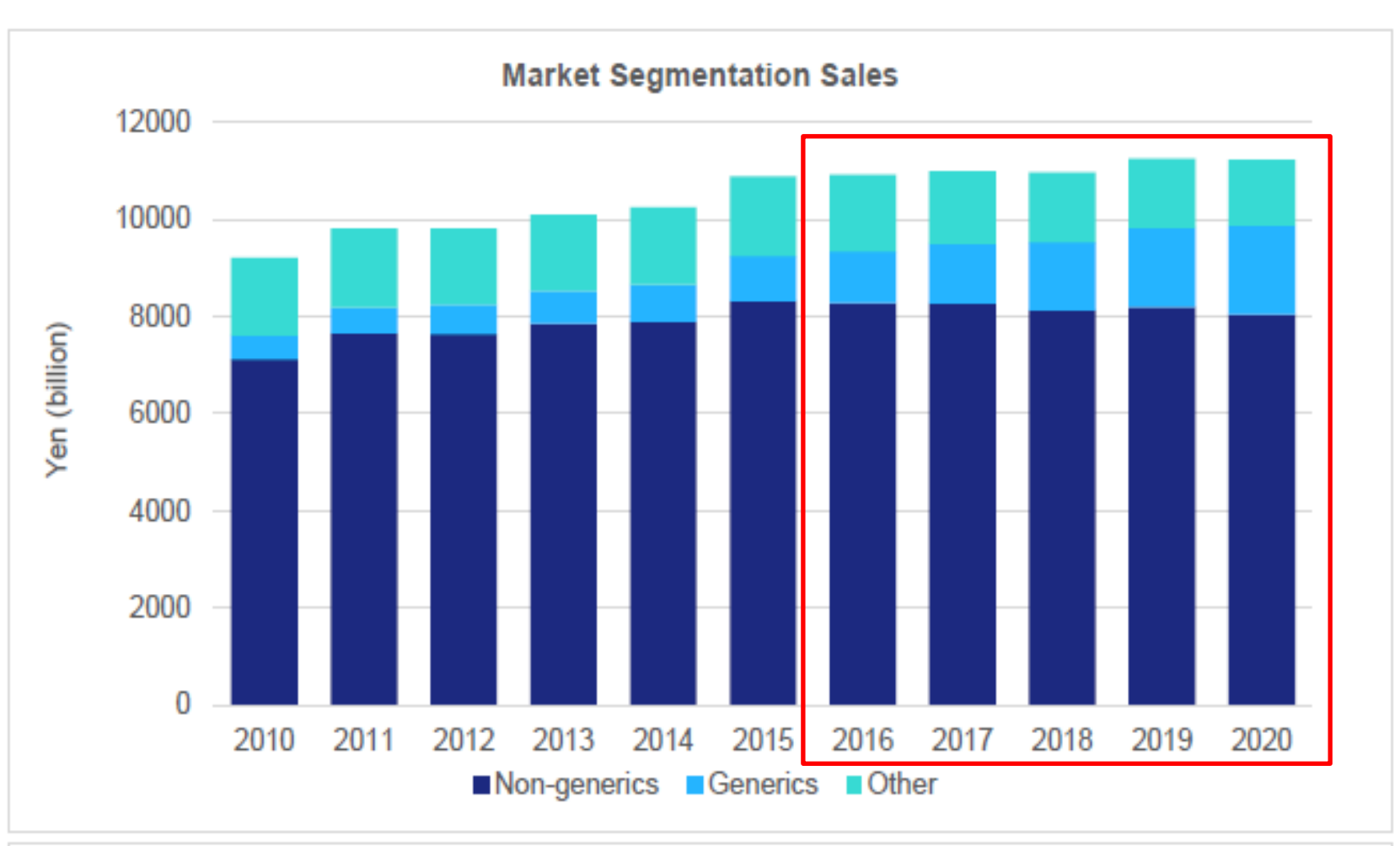
…While at the same time the average peak sales per asset has

DECREASED BY 48%



Source: Deloitte's "Measuring the return from pharmaceutical innovation 2015: Transforming R&D returns in uncertain times"
http://www2.deloitte.com/uk/en/pages/life-sciences-and-healthcare/articles/measuring-return-from-pharmaceutical-innovation.html

Spending on pharmaceuticals in Japan will remain flat over the next five years



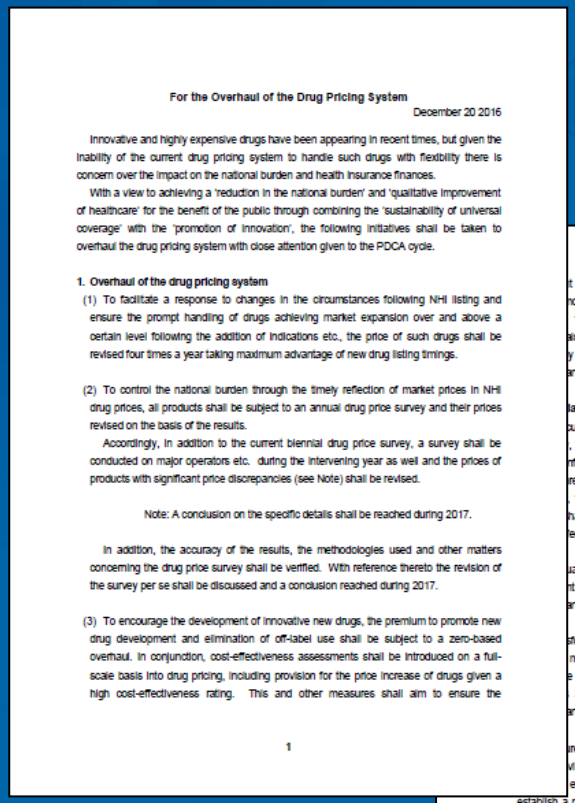
Source: IMS "Market Prognosis 2016-2020- Asia/Australia-Japan"

Japanese Pharmaceutical Prices Fell Below the EU(*) average in Recent Years

Listed year	2011	2012	2013	2014	2015	2016	Total
Median of the ratio (Japan to Europe)	1.13	1.25	1.03	0.80	0.80	0.89	0.99
Number of products	28	18	28	27	26	19	146

* Incl. UK, Germany and France

Drastic Change in Drug Pricing could Lead to Risk



For the Overhaul of the Drug Pricing System

December 20 2016

Innovative and highly expensive drugs have been appearing in recent times, but given the inability of the current drug pricing system to handle such drugs with flexibility there is concern over the impact on the national burden and health insurance finances.

With a view to achieving a 'reduction in the national burden' and 'qualitative improvement of healthcare' for the benefit of the public through combining the 'sustainability of universal coverage' with the 'promotion of innovation', the following initiatives shall be taken to overhaul the drug pricing system with close attention given to the PDCA cycle.

1. Overhaul of the drug pricing system

(1) To facilitate a response to changes in the circumstances following NHI listing and ensure the prompt handling of drugs achieving market expansion over and above a certain level following the addition of indications etc., the price of such drugs shall be revised four times a year taking maximum advantage of new drug listing timings.

(2) To control the national burden through the timely reflection of market prices in NHI drug prices, all products shall be subject to an annual drug price survey and their prices revised on the basis of the results.

Accordingly, in addition to the current biennial drug price survey, a survey shall be conducted on major operators etc. during the intervening year as well and the prices of products with significant price discrepancies (see Note) shall be revised.

Note: A conclusion on the specific details shall be reached during 2017.

In addition, the accuracy of the results, the methodologies used and other matters concerning the drug price survey shall be verified. With reference thereto the revision of the survey per se shall be discussed and a conclusion reached during 2017.

(3) To encourage the development of innovative new drugs, the premium to promote new drug development and elimination of off-label use shall be subject to a zero-based overhaul. In conjunction, cost-effectiveness assessments shall be introduced on a full-scale basis into drug pricing, including provision for the price increase of drugs given a high cost-effectiveness rating. This and other measures shall aim to ensure the

1

t of innovation through the proper identification of genuinely effective drugs
ote investment in R&D.
for the full-scale introduction of cost-effectiveness assessments, with
lso to expert knowledge, the modality for the conduct of the assessments
y organizations and frameworks with an independent standpoint shall be
nd a conclusion reached during 2017

latives to be taken alongside reform

uracy and transparency of drug pricing formulae shall be fully assured.
, with consideration given to information regarded by pharmaceutical firms as
nfidential, measures to clarify the basis of drug price calculations and promote
rency of the drug pricing process shall be discussed and a conclusion reached.
the foreign average price adjustment method for high-cost drugs etc. In
hall be improved through more accurate identification of the foreign price with
erence to system variations.

ual business conditions of parties affected by the drug pricing reform shall be
ntified and actions to take where necessary based on the findings shall be
nd a conclusion reached.

sform Japan's pharmaceutical industry from the current long-listed product-
model into a structure bearing greater drug discovery capability, measures to
e R&D support for innovative biologics and biosimilars, support venture
and promote market competition among generic manufacturers shall be
nd a conclusion reached.

re stable drug supplies, greater efficiency in distribution shall be achieved
ving consideration to the actual business conditions of operators while
efforts to improve distribution practices and taking appropriate action to
establish a profit structure in line with the market environment. To facilitate appropriate price formation, effective measures to promote single-product, single-price transactions and early settlements in particular shall be discussed and a conclusion reached.

(5) Measures to ensure the prompt delivery of novel health technologies with an established reputation to patients shall be discussed with reference to their cost-effectiveness.

2

Conclusion

What is at stake?

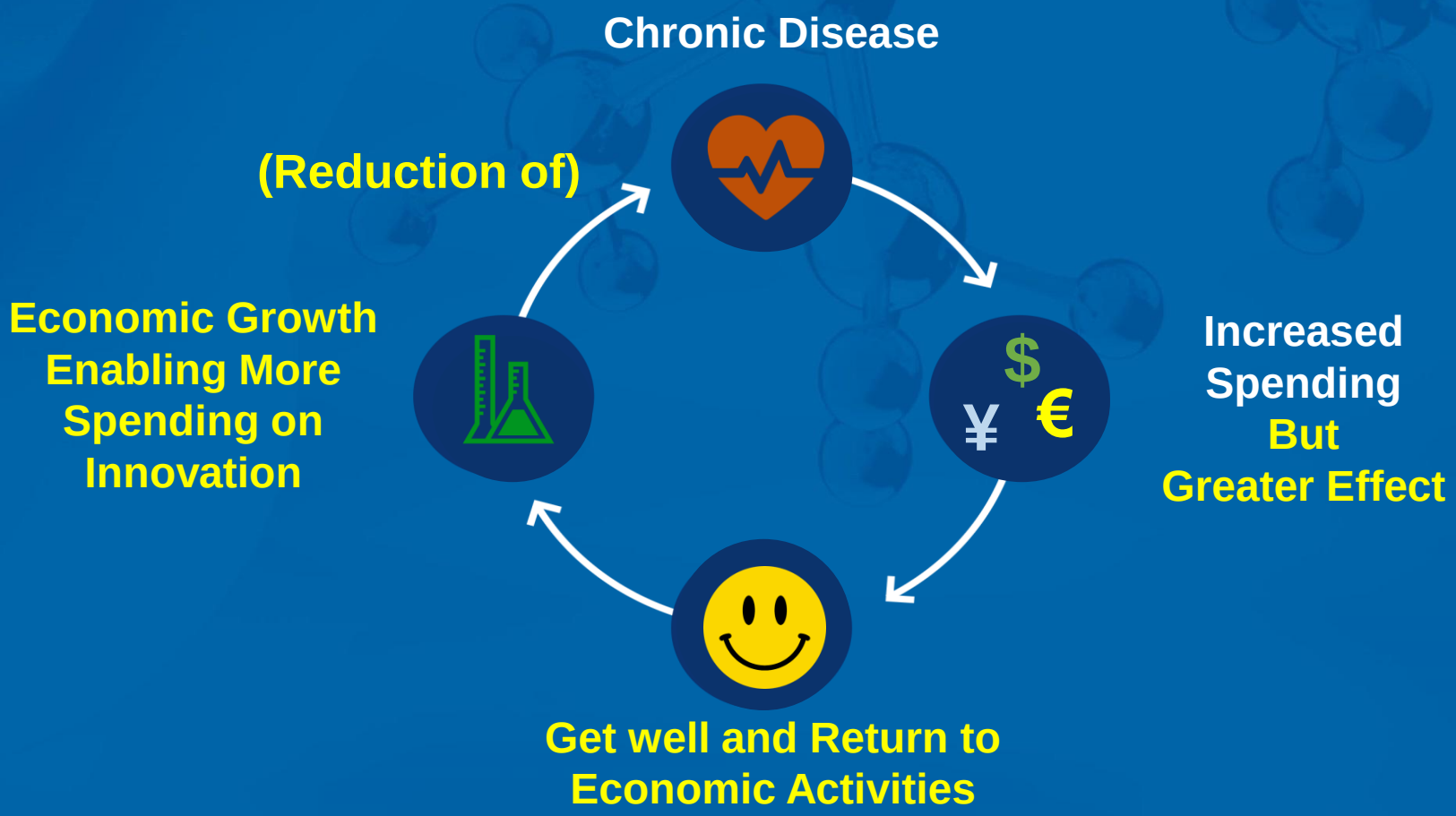
- Japanese patient access to the newest medicines (drug lag)
- Japan's reputation as a pro-innovation and predictable investment destination
- Potential for economic growth in sector
  - ✓ R&D investment
  - ✓ Successful move up the innovation value chain for domestic companies
  - ✓ More jobs

How Can We Address Total Health Care Costs?

- To maintain the Japanese healthcare system, we must consider financial stability of the system
- At the same time, here still exist significant unmet medical needs and we might be able to treat/cure those moving forward
- We, PhRMA believe that we need to strike a balance between...

Sustainability of better outcomes, better access, and continued innovation

The Need to Seek a New Health Care System to Keep Pace With Innovation



Conclusion

Challenges: Japan has the highest proportion of older adults in the world, increased instance of chronic disease, and cost pressures

- ✓ Key challenge is finding the correct balance between pro-innovation policies and cost containment
- ✓ Major reforms undertaken too quickly and without consultation with relevant stakeholders may yield unintended consequences

Conclusion

Goal: For the Japanese government to achieve goals, PhRMA is committed to

- ✓ Continue to provide Japanese patients with the world's most innovative medicines in the earliest timeframe
- ✓ Strongly support efforts to build upon recent successes and maintain the long-term stability of Japan's world-renown healthcare system
- ✓ Focus on ensuring that the Japanese biopharmaceutical sector achieves its full potential

Conclusion: Reform to the System Must Involve Stakeholders

- Sweeping changes to the drug pricing system -- under consideration
- Rationale for contemplated changes clear -- process and outcome remain unclear
- Comprehensive reform of this magnitude -- only succeed if all stakeholders, including Pharmaceutical industry, are involved in a meaningful way

PhRMA is willing to work with the Japanese government proactively to achieve mutual goals