



PhRMA Press Conference

The 2018 Pricing Reform

– Assessing Where We Stand and
Charting a Pro-Innovation Pathway Ahead –

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Patrik Johnson, JBEC Chairman

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Pro-Innovation Policies have Activated R&D in Japan and Accelerated Patient's Access to Innovative New Medicines, but the Future is Uncertain

Pro-Innovation policies implemented in the past decade

2007
5 year strategy for development of innovative medicines: **PMDA announced to double the number of reviewers**

2010
Pilot introduction of PMP
Introduced a **mechanism to maintain the price during patent period**, while accelerating switch to generics after LOE at the same time

2014
Announced the launch of **Sakigake Review System**

2015
AMED established Pharma Industry Strategy

2017
Drastic Pricing Reform

2018-
Create Uncertainty for the future

Positive outcomes of past pro-innovation policies



For 3 years in a row since 2014, PMDA has **achieved the world's fastest review phase time (median) for NMEs¹**



Percentage of "NDA filing lag less than 1 year" increased from 18% in 2006-2009 (before PMP) to 71% in 2015-2018 (includes projection)²



The **number of approved new medicines increased by 42%** between 2007-2011 and 2012-2016³

2018 Pricing Reform Package

Balance between “sustainability of NHI” and “promotion of innovation” has not been achieved

Price Maintenance Premium

- **Limits the scope by narrowly defining innovation** (920→540 products or 40%)

Quarterly repricing

- **Re-priced quarterly** based on market expansion re-pricing rule **when annual NHI sales >35B yen**

Reward for Innovation at Listing

- Increased premium for cost-plus pricing

Foreign Price Adjustment

- Changed US price benchmark
- Limited the scope of application

Cost Effectiveness Assessment

- Price for 7 pilot drugs to be **adjusted in April 2018**
- **Development of a “full-scale” HTA system to be completed by end of FY 2018**

Long Listed Products

- **Stepwise price reduction toward generic price level beginning 10 years after loss of exclusivity**

Generics

- **Single price band for generics after 12 years** from launch

Annual Price Survey and Revision

- Based on the results of price revision for all products during 2018-2020, **scope of off-year revision will be decided in 2020**

Impact of 2018 Pricing Reforms on R&D



Among developed markets, Japan forecasted to become the only market to see negative growth in mid-long term



Reduced price and business predictability due to change in PMP product requirements; uncertainty remains for the future (HTA, annual price revision)



Risk of declined global competitiveness as a market to attract R&D investment

The Innovative Biopharmaceutical Industry: A Responsible Partner in Healthcare

- PhRMA remains committed to working with the Japanese government as a true partner to promote pro-growth and pro-innovation policies for the benefit of Japanese patients, companies and economy.
- To this end, we ask the Japanese government to:
 1. Revisit the Price Maintenance Premium
 2. Develop a HTA system, based upon learnings of other countries, that does not impede patient access to needed medicines
 3. Maintain the biennial price revision system for innovative products
 4. Ensure policies are developed in a fair and transparent manner that allows for meaningful input from all stakeholders