Comprehensive approach for Innovation in Japan

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厚生労働省
Ministry of Health , Labour and Welfare

pmda

Outline

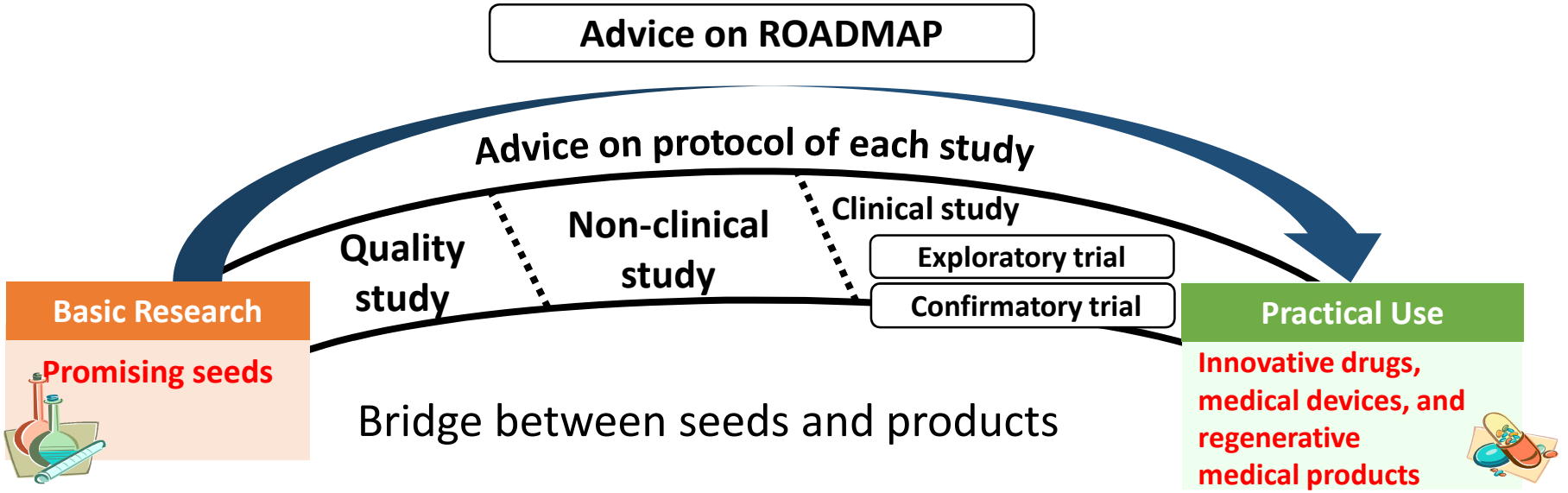
Innovation

- Strategic consultation
- Optimization of drug administration
- Identification of value

Value creation

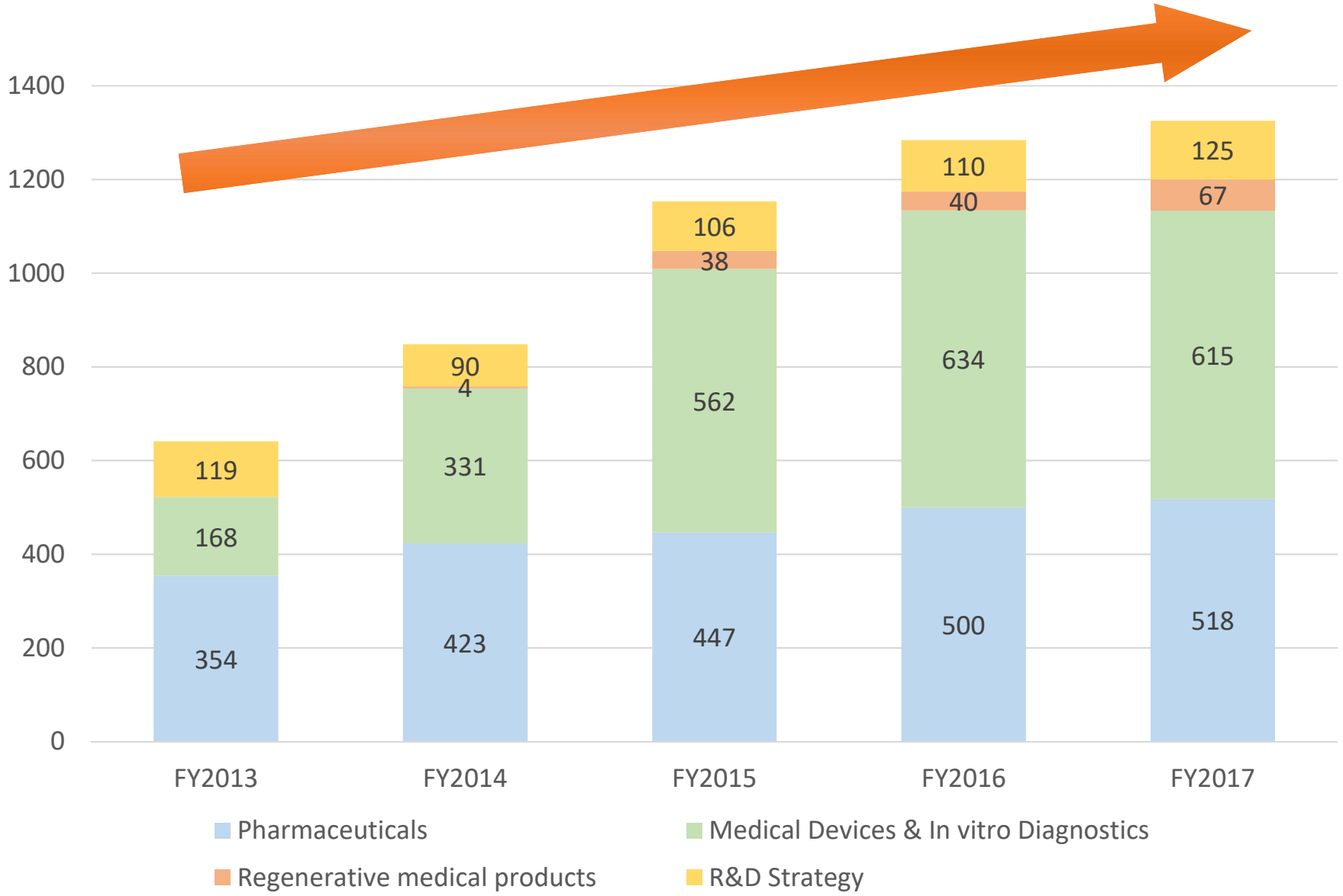
Enhanced Pharmaceutical Affairs Consultation on R&D Strategy

- Facilitate development of medical products by academia by developing more reliable ROADMAP.
- Contribute to promotion of clinical trials led by academia.



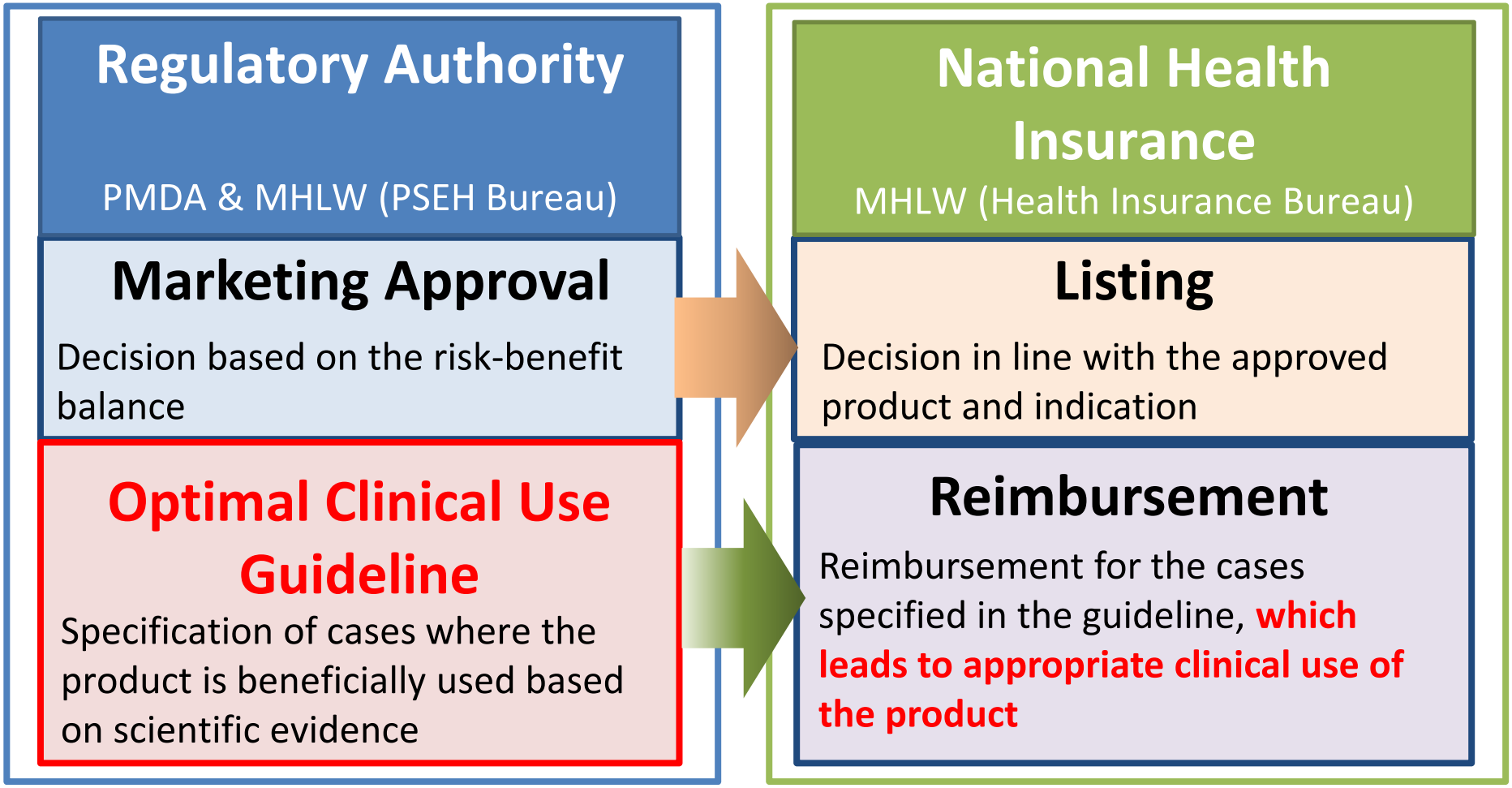
*** In collaboration with the Japan Agency for Medical Research and Development (AMED), PMDA will proactively support establishment of an exit strategy via Pharmaceutical Affairs Consultation on R&D Strategy.**

Number of Consultations by PMDA



Utilization of Guidelines in National Health Insurance System

~ Cooperation between RA and NHI~



Appropriate Use Committee for elderly patients

- To optimize drug therapy for elderly people (Avoid drug adverse events, improve medication adherence).
  The Guidance compiles points to consider for practicing better medicine therapy that takes into consideration of the characteristics of elderly people.
- The guidance is intended to provide reference information on for medical care and prescription.
- While focusing on patients over 65 years old, emphasis is placed on elderly people aged 75 and older

Guidance of Appropriate Medication for elderly patients（general）released on 29 May 2018

Introduction

1. Concept of polypharmacy
2. Current Status of Multiple Drug Administration
3. Basic concept of drug prescription review and flow chart
4. Diagnosis and adverse events to pay attention to when taking multiple drugs, which trigger prescription review
5. Points to consider regarding administration of medication to the elderly
6. Support for medication
7. Collaboration in multiple health professionals/medical institutions and communities
8. Foster national understanding

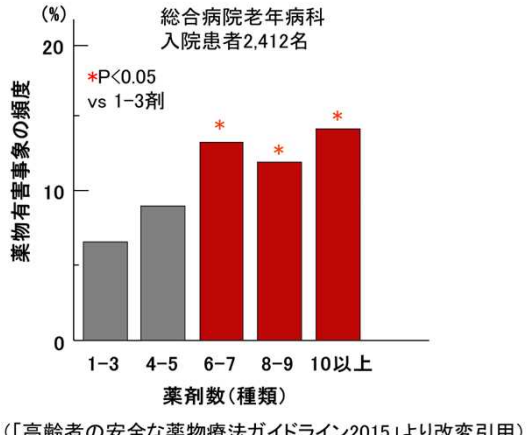
APPENDIX Basic point to consider on medicines commonly used in elderly etc.

【Two step approach of guidance development】

○ FY2017 ：guidance（general）

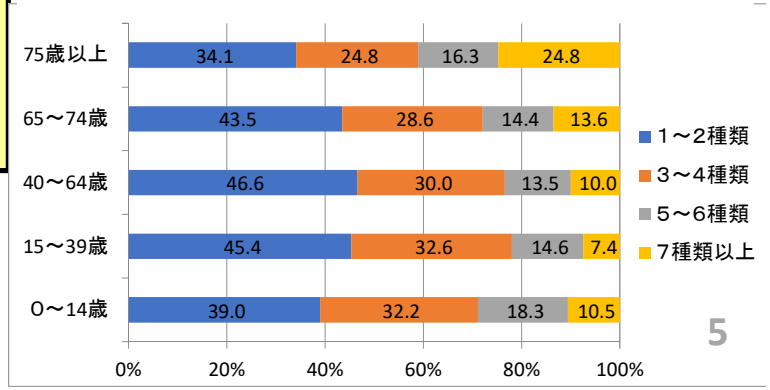
○ FY2018： medical care environment specific guidance

Number of pills and AEs



（「高齢者の安全な薬物療法ガイドライン2015」より改変引用）

Number of dispensed drugs for a person at one pharmacy (2016)

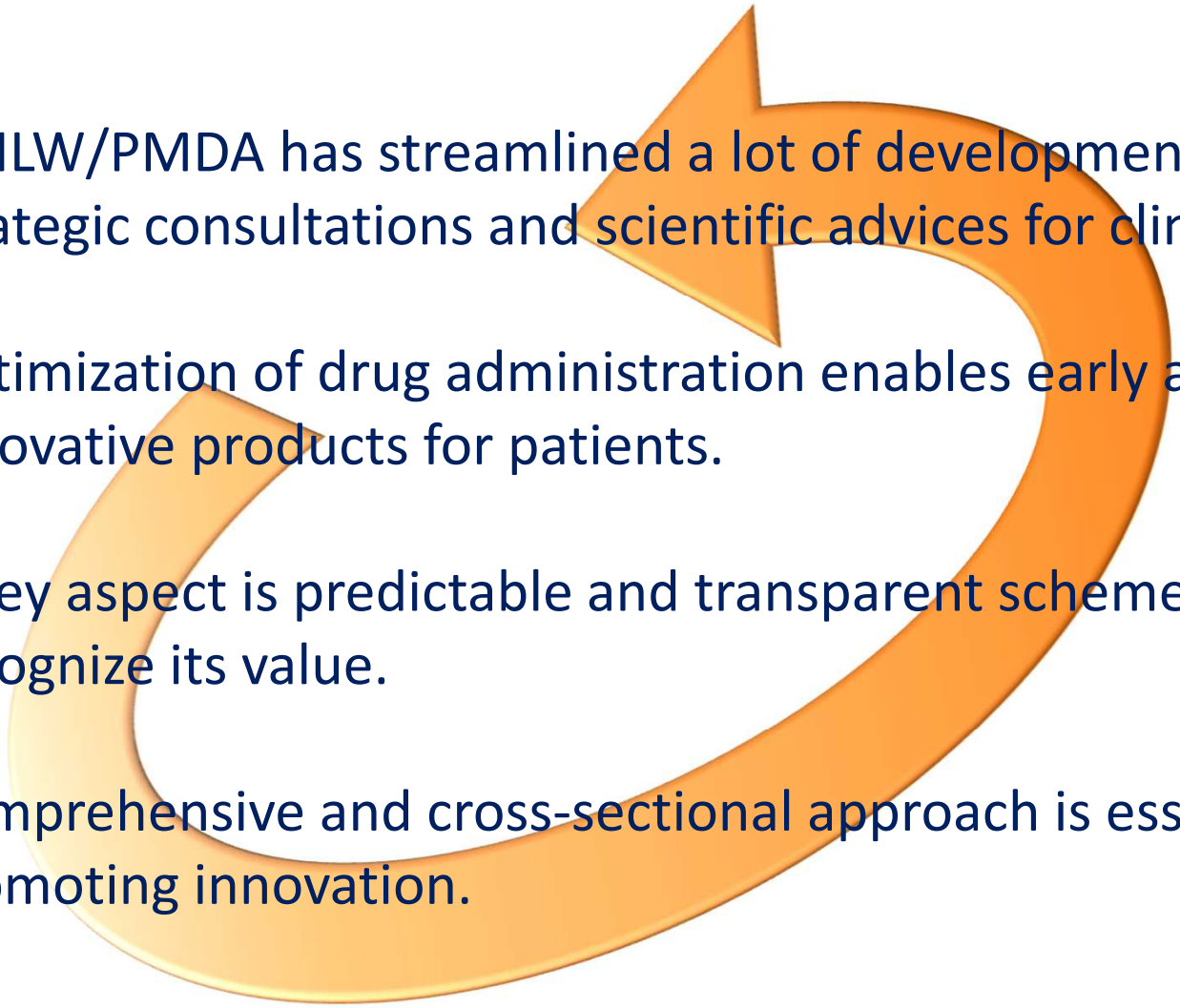


Premium Pricing in National Health Insurance System

- Some premiums are applied to innovative products according to its value
- SAKIGAKE designated products are admired in Japanese Health Insurance System

Type	Addition ratio	Target products
Innovativeness premium	70-120%	New action mechanism, high efficacy/safety, improvement of disease treatment method
Usefulness premium	5-60%	High efficacy/safety, improvement of disease treatment method
Marketability premium	5%, 10-20%	Orphan drug, etc.
Child premium	5-20%	Dosage and usage expressly includes those pertaining to children, etc.
SAKIGAKE review designation scheme premium	10-20%	Pharmaceutical approval was obtained in Japan ahead of other countries, etc.

Conclusion



- MHLW/PMDA has streamlined a lot of developments through strategic consultations and scientific advices for clinical trials.
- Optimization of drug administration enables early access to innovative products for patients.
- A key aspect is predictable and transparent scheme to recognize its value.
- Comprehensive and cross-sectional approach is essential for promoting innovation.

Thank you for your attention!