The Biosciences industry in Japan: Why and how does the Government support a strategic sector for the country?

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Topics

• Why does the government support the strategic sector for the country?
  – Loss of competitiveness
  – Strong unmet medical needs still exist
  – The Year 2025+ problem

• How will/does the government support the strategic sector for the country?
  – Higher incentives
  – Quicker approval decision for drugs
  – New national framework for medical R&D
  – Support for the future; regenerative medicine
  – Clearer pricing criteria
  – Broad National healthcare insurance coverage
Development of innovative AND cost-effective drugs/devices/therapies are absolutely essential
How will/does the government support the strategic sector for the country?

1. Higher incentives
2. Quicker approval decision for drugs
3. “SAKIGAKE” Designation System
4. New national framework for medical R&D
5. Support for the future
1. Higher incentives (1)

(Existing drugs)

• “Premium for promotion of new drug creation and resolution of unapproved drugs/indications”
  – In Japan, NHI prices of drugs/devices are designed to drop every two years
  – By maintaining the price (premium pricing) of the forerunner product in the patent period, the resource for next development can be secured earlier, enabling promotion of development of new drugs and unapproved drugs/indications and earlier responses to needs of patients and healthcare professionals.
(Newly listed drugs)

1. Higher incentives (2)

- Higher premium for innovative drugs
  - Up to 120%, compared to the current NHI price of its comparative drug
  - For example, + 100% premium for Sovaldi (Gilead Sciences), compared to the comparable combination of drugs

- “SAKIGAKE” premium
  - When a company launches a new drug first in the world, the drug will gain additional “premium.”
  - “SAKIGAKE” means “taking the lead [initiative],” “being the first”
2. Quicker approval decision

- No more “Drug lag”
  - “Drug lag”: Delay in launching new drugs that are already approved outside Japan
3. SAKIGAKE Designation System

- **SAKIGAKE Designation System**: promoting R&D in Japan aiming at early practical application for innovative pharmaceutical products, medical devices, and regenerative medicines.
  - “SAKIGAKE” means “taking the lead [initiative],” “being the first”
4. New national framework for medical R&D

- Expected functions for Japan Agency for Medical Research and Development (A-MED)
  ① Management of medical R&D
  ② Management of data produced from clinical research and trials
  ③ Support for practical application
  ④ Support for improving R&D infrastructure
  ⑤ Promotion of international strategy
5. Support for the future: Regenerative medicine

- A new framework has been designed to dramatically accelerate the development of new regenerative medicine therapies
  - Conditional (tentative) approval

- In November 2013, the National Diet revised Japan's Pharmaceutical Affairs Law, implemented in 2014
  - Pharmaceutical and Medical Device Act
  - The new law is expected to help Japan to be a leader in regenerative medicine in the years ahead
Other important policies

• **Clearer** pricing criteria
  – “Point system”

• **Broad** National Healthcare Insurance coverage
  – Almost all approved drugs/devices are fully covered by National Healthcare Insurance
Key take-home messages

• There are many and fundamental reasons why the Japanese government supports the biosciences industry in Japan, not only home companies but also foreign ones.
  – Development of innovative AND cost-effective drugs/devices/therapies are absolutely essential

• The Japanese government has recently seriously supported and will support the strategic sector through many ways, competing with other countries, in spite of its severe financial constraints