Overview of the 5-Year Strategy for the Creation of Innovative Pharmaceuticals and Medical Devices

To provide our populace with access to the best pharmaceuticals/medical devices in the world

To boost the pharmaceutical/medical device industry to become the driving force of Japan's growth

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⊙ Ministry of Education, Culture, Sports, Science and Technology,
Ministry of Health, Labour and Welfare,
Ministry of Economy, Trade and Industry

Measures aiming for development originating in Japan and Japan's participation in simultaneous global development

1) Concentrated Research Financing

- Prioritization and expansion of budgets related to the development of pharmaceuticals and medical devices
- Creation of organizations to moderate the focal R&D by business-academia-government collaborations
- Deliberations on the improvement and enhancement of the R&D tax system

2) Nurturing Ventures, etc.

- Expansion of research funds
- More common use of facilities/equipment, etc.
- Development of a system to support commercialization, utilization of retired human resources, improvement/ development of hotlines, etc.
- Deliberation of support for application fees
- Deliberation on measures to invigorate the delivery of medical device materials/parts

3) Improvement of the Clinical Research/Trial Environment

- Promotion of international clinical trials
- Development of 'medical clusters' that promote clinical and practical research through close cooperation between business, academia and government, primarily centering on the National Center for Advanced and Specialized Medical Care, in order to address conditions that significantly affect the national populace
- Development of translational research centers, centers for regenerative medicine and the clinical research system
- Centralization of clinical trial sites, creation of networks and increased use of IT with a primary focus on the medical clusters
- Development and securing of physicians as well as HR able to support clinical studies
- Efforts to improve the assessment of clinical achievements by physicians, etc.
- Promotion of rationalization of clinical research regulations

4) Collaboration with Asia

- Promotion of joint research on important diseases/conditions
- Joint research on methods to utilize data gathered in East Asia

5) Faster and Better Reviews

- Shortening of the time to launch a new drug by 2.5 years (elimination of the drug lag)
- Doubling in the number of new drug review staff (in 3 years by 236) and improve the review quality
- Clarification of the ideal review process and review standards as well as improvement of GCP utilization
- Creation of guidance on international clinical trials, implementation of a priority clinical trial consultation system
- Deliberation on the introduction of joint clinical trial consultation by review authorities in Japan, Europe and the U.S.
- Promotion of clinical trial/research rationalization and simplification, while maintaining the safety of medical devices
- Expansion and improvement of medical device review staff
- Improvement in the operation of medical device GCP

6) Appropriate Assessment of Innovations

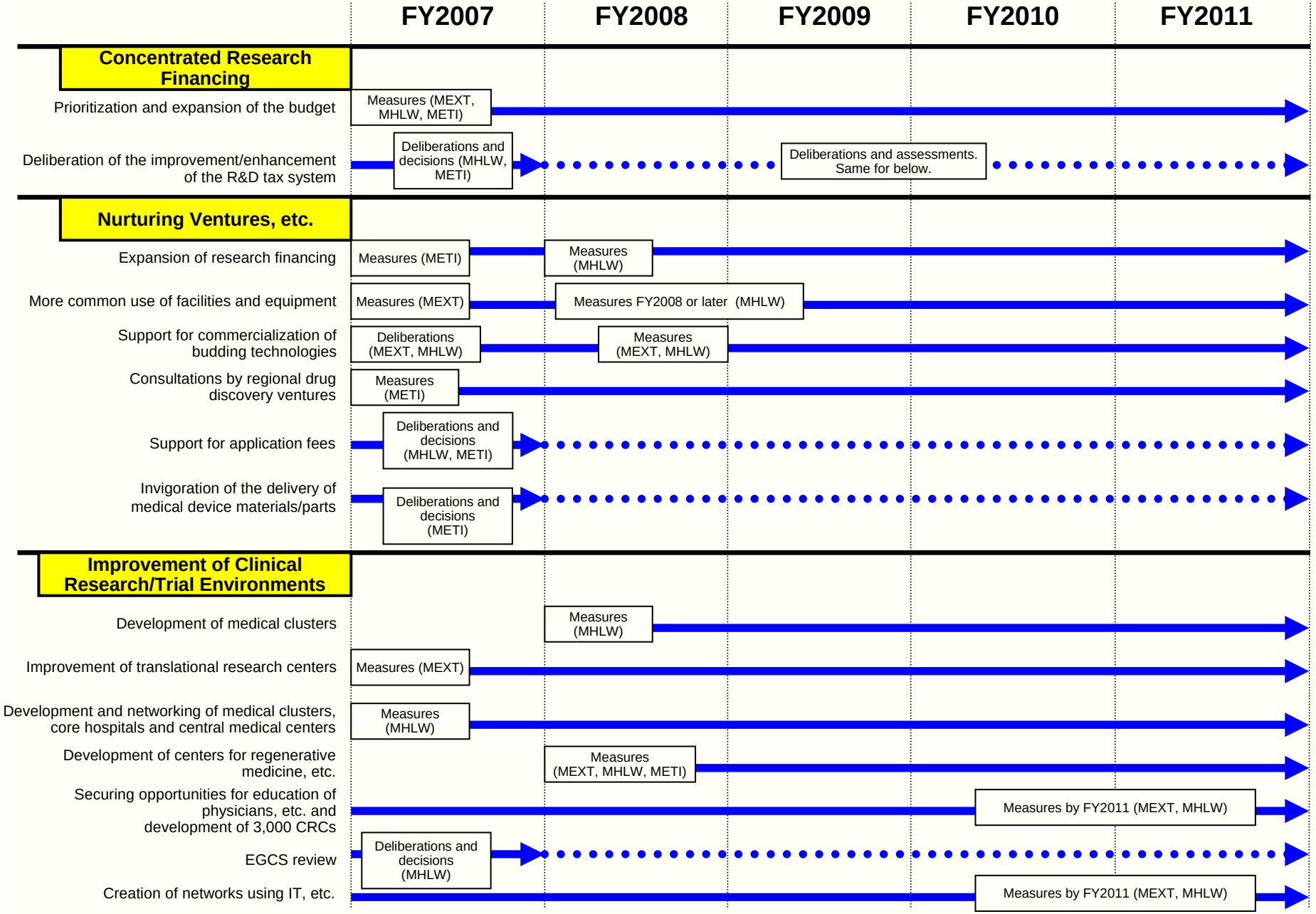
Deliberation on more appropriate assessment of innovative pharmaceuticals in relation to the drug pricing system, etc.

7) Public-private dialogue

Intensified collaboration between related ministries, research institutes and industries

Implementation of regular public-private dialogue

A roadmap to the primary activities in the 5-year strategy (I)



A roadmap to the primary activities in the 5-year strategy (II)