Overview Overview of the Five-Year Strategy for Creation of Innovative Drugs/Medical Devices

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Cabinet Office
Ministry of Education, Culture, Sports, Science and Technology

Provide the world's leading drugs/medical devices to the people

Making drugs/medical devices the driving force of growth in Japan

Group of measures aimed at up-front development in Japan or simultaneous worldwide development with participation from Japan

(1) Intensive investment of research funds
- Focused allocation/expansion of drugs/medical devices related budget
- Establishment of an organization to make adjustment on intensive development areas by industry, academia, and public sector.
- Discussion on improvement/enhancement of research and development taxation system
- Discussion on comprehensive/efficient management of research funds in special zone for advanced medical care development
- Focused/centralized distribution of research funds related to special zone for advanced medical care development

(2) Development of venture business
- Expanding research funds
- Joint use of facilities and devices ÅEDevelopment of industrialization support system, utilization of experienced human resources, improvement of consultation
- Improvement of support measures for utilization of the "angel taxation" system
- Implementation of support internationalization of Bio-Venture
- Promotion of industrialization of new technologies that are important for national economy
- Discussion on support for examination expenses
- Discussion on measures to facilitate offering of medical devices

(3) Development of environment for clinical research/trials
- Promotion of joint international clinical trials
- Establishment of “medical cluster”, a system in which National Center for Advanced and Specialized Medical Care conduct clinical reserach in close cooperation with industry, academia, and public sector
- Establishment of bridging research support facilities, regenerative medicine facilities, and clinical research system
- Utilization of facilities, networks, and IT in clinical trials led by medical clusters
- Training/securing human resources to support doctors and clinical trials
- Measures to improve clinical performance evaluation of doctors
- Promotion of appropriate regulations of clinical research
- Establishment of global clinical research facilities with central IRB functions for enabling advanced joint international research
- Establishment of conference for dual track talk from development stage between parties on research/development side and regulation side in special zone for advanced medical care development

(4) Cooperation with Asian countries
- Promotion of joint research on diseases of importance
- Joint research on utilization of data collected in east Asia

(5) Speeding up and quality improvement of examination
- Reducing the period before marketing for drugs by 2.5 years (elimination of drug lags)
- Doubling the number of drug examination staff and quality improvement (increase of 236 staff members over 3 years)
- Clarification of the examination approval processes and standards and improved execution of GCP (Good Clinical Practice)
- Establishment of a consultation system for clinical trials for handling every consultation in timely manner
- Discussion on the introduction of a consultation system for joint clinical trials among executives of Japan, the United States, and Europe
- Reducing the period before gaining approval of new medical devices by 19 months (elimination of device lags)
- Increasing the number of medical device examination staffs and quality improvement (increase of 69 members in 5 years)
- Introduce 3-track examination system for new medical devices/innovated medical services/generic medical devices, and promote rationalization of approval examination.
- Improving quality and quantity of consulting operation.
- Improved execution of GCP for medical devices

(6) Proper evaluation of innovations

More proper evaluation of innovative products in drug pricing system

(7) Government and private sector discussion

Enhanced cooperation among related ministries, research institutions, and industries

Implementation of regular government and private sector discussion