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

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
❍Ministry of Health, Labour and Welfare
Ministry of Economy, Trade and Industry

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
- Promotion of rationalization and simplification of clinical approval trials/examinations while securing the safety of medical devices
- Improvement/enhancement of examination/consultation system of medical devices
- 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