Council of the Concept for Early Prevalence of the Novel Drugs to Patients by Improving Drug Discovery Capabilities

Interim Report Executive Summary

(Recognition of Current Situation)

As top-selling drugs shift from small molecule compounds to novel modalities, such as biologics, and drug discovery methods become more increasingly complex, the decline of international competitiveness of Japanese pharmaceutical companies and new drug lag/drug loss issues are indicated. To catch up with global trends, we hereby outline an overall and comprehensive plan regarding the "drug discovery capabilities" of Japan, along with industry, government, and academia, and will strongly promote the policy for the pharmaceutical industry as an important growth industry of Japan.

(Strategic Goals)

We set three strategic goals to enhance drug discovery capabilities of Japan. We will set certain indicators to ensure achievement of these strategic goals, and will continuously evaluate their progress.

First, we will promote the development of the innovative drugs for all patients, even if it is not profitable drugs, such as rare diseases.

Second, to ensure Japan's global position in drug discovery, we will establish a nurturing environment and system for academia and startups, with consistent support from the early research & development to the clinical application. These efforts are also important from the viewpoint of the security of Japan. We should work widely around the world to gather excellent human resources and funds.

Third, by reforming the pharmaceutical industry structure and improving the investment environment, we aim to create a social system that allows continued cyclical development of investment and innovation. At the same time, we will promote well-balanced measures from mid- to long-term perspectives by considering the positioning of common treatment to self-care.

Based on these, we should promote the following measures:

(Strengthen the Drug Discovery Capabilities of Japan)

Drug discovery requires a broad range of R&D capabilities, from basic research to clinical application, as well as comprehensive facilities, such as social systems and regulations. We will adopt comprehensive and realistic measures toward the enhancement and development of all personnel, related industries, and clinical functions that constitute the drug discovery ecosystem, which, while customized for Japan, are based on international viewpoints.

Human resources that can lead exit-oriented R&D in cooperation with various stakeholders

- Proactive recruitment and utilization of human resources with foreign experience with know-how for commercialization and funding
- Organization of public-private committee, including foreign-affiliated companies and venture capitals (the government and companies commit to policies and activities in Japan)
- Organization of matching events of academia/startups in and outside Japan to pharmaceutical companies and VCs.

International-Competitive Clinical Trial Implementation System

- Establishment of the implementation system for first-in-human studies
- Promotion of contribution of clinical research core hospitals to drug discovery
- Promotion of multi-regional clinical trials
- Support for development of human resources engaged in clinical trial operations and improvement of their career track
- Support for implementation of clinical trials in Japan by overseas companies
- Making review by single IRB a principles/Promotion of DCT/Disclosure of information and promotion of public understanding

Manufacturing system for new modality drugs

- Strengthening support for CDMOs and development of human resources for bio-manufacturing, including their engage from overseas
- For international-level CDMOs, integration with core sites conducting FIH studies and/or collaboration with overseas core sites

Constant creation and growth of seeds in academia and startups

- Enhancement of research and development support for academia and startups, establishment of intellectual property/business strategies
- Promotion of basic research to maintain and improve sustainable drug discovery capabilities
- AI and robotics combined with drug discovery and conversion science, regenerative medicine, cell and gene therapy, etc.
- Creation of a suitable environment for medical DX and improved research and development capabilities of university hospitals, etc.

(Prompt Delivery of Novel Drugs to Patients)

In order to meet the expectations of patients and their families who are waiting for the development of novel drugs, we will take proactive measures, including reviewing pharmaceutical regulations, improving their operations, and encourage global pharma, while grasping the fields and causes where novel drugs are difficult to develop.

Review of pharmaceutical regulations

- Review of pharmaceutical regulations in light of multi-regional clinical trials and transmission of such information to foreign countries

Development of drugs for pediatric and intractable diseases and orphan drugs

- Development of drugs for intractable diseases/orphan drugs that are less profitable

PMDA's Consultation/Review System

- Consultation and support to promote the clinical application of new modality drugs
- Promotion of globalization, such as wide anglicization of related process and documents and participation in the framework of international joint review
- Dissemination of the information that the pharmaceutical regulations in Japan are open internationally

(Construction of a Social System That Can Sustain the Cycle of Investment and Innovation)

It is important that the entire system becomes sustainable while it can deal with diversification of patient needs, introduction of new technologies, in addition to activate the entire medical market, maintaining harmony between the pharmaceutical market and economies and finances.

- Appropriate evaluation for the value of innovative drugs
- Departure from dependence on long-listed products
- Promotion of the use of biosimilars
- Promotion of self-care and self-medication by supporting switch to OTCs, etc.
- Effective utilization of private insurance, in addition to public insurance, for new treatment
- Strengthening of support for startups in the healthcare field