

## Section 6. Promotion of Creating Innovative Pharmaceuticals and Medical Devices

With the aim of being the top management industry, the government, and academics are sharing ideas on the direction of various measures should take in creating innovations and enhanced international competitiveness for industry in the area of pharmaceuticals in Japan with the “government and private sector discussion on innovative drug development” being held since 2007 and run by the Minister of Health, Labour and Welfare and participated in by the Minister of Education, Culture, Sports, Science and Technology, the Minister of Economy, Trade and Industry, and participants from the pharmaceutical industry as well as education and research institutions. At the second government and private sector discussion (April 2007), the “5-Year Strategy for Creating Innovative Drugs and Medical Devices” was formulated and published as a uniform policy package to support the entire process from research through to practice. Discussions between the government and the private sector have continued to be held and efforts are being made in steady implementation of the 5-year strategy.

Furthermore, the Ministry of Health, Labour and Welfare formulated the “New Vision for the Medicine Industry” on August 30, 2007 and described measures to be taken by the government in the future in the form of an action plan based on the 5-year strategy along with the future image of the pharmaceutical industry. Hereafter the government and private sector will follow up on the action plan on an annual basis.

In addition, to provide support from the research and developmental side, a “New 5-Year Clinical Trial Activation Plan” was formulated in conjunction with the Ministry of Education, Culture, Sports, Science and Technology in March 2007. 6 bridging research support facilities, 10 core hospitals, and 30 core medical institutions were selected for the establishment of an environment where clinical research and the promotion of clinical trials can take place. Additional efforts are also being made by the independent administrative organization of the National Institute of Biomedical Innovation in supporting venture enterprises to create pharmaceuticals that are difficult to achieve by private enterprises alone.

Furthermore, to cope with patients’ needs for advanced medical services, an advanced medical care assessment system was established in April 2008. In this system advanced medical technologies using pharmaceuticals or medical devices that are yet to be approved under the Pharmaceutical Affairs Law can be combined with insurance provided that they meet certain requirements.

Advanced medical care research facilities have also been selected in establishing “special zones for advanced medical care development” for promoting the development of state-of-the-art regenerative medicine, pharmaceuticals, and medical devices in parallel consultations between the

Ministry of Health, Labour and Welfare who controls the research fund and the independent administrative organization of the Pharmaceuticals and Medical Devices Agency.

Through these efforts the necessary measures will be taken to achieve a further improved health care level by providing high quality, safe and secure pharmaceuticals and medical devices.