Japan's Medical/Assistive Device Industries: How METI Aids Their Development

By Akira MASUNAGA

1. Introduction

The medical equipment and assistive device industries assume an important role in supporting medical care and health in Japan, where the population is rapidly aging amid a falling birthrate. They are supposed to provide an impetus to the country's future economic growth as leading industries. This report introduces policy measures the Ministry of Economy, Trade & Industry (METI) is pursuing to assist the development of both industries.

2. Policy on Medical Device Industry

(1) Medical devices

METI sees it as imperative to promote research and development of medical devices using cutting-edge technology to accelerate the growth of the medical equipment industry and enhance the quality of life for patients. Government departments concerned, taking advantage of their own strong points, have implemented various measures to encourage the development of innovative technologies that can be applied to medical devices. METI thinks that further promotion of technology development requires closer mutual collaboration in better dealing with relevant inter-ministerial problems. From this point of view, METI is carrying out the development projects listed below in cooperation with the Ministry of Health, Labor & Welfare and the Ministry of Education, Culture, Sports, Science & Technology.

***R&D on Intelligent Surgical Instrument**

By relying on blue-chip sensing and image-processing technologies, this project aims to develop an endoscope-guided device that can be used in both diagnosis and surgery on cancer patients. It should be useful in locating cancer cells and cutting them off with the minimum necessary surgery. *(Fiscal 2007-2011)*

***R&D on Drug Delivery System (DDS) for Treatment of Malignant Tumors**

This nanotechnology-based system is designed to pinpoint a tumor cell, deliver anticancer agents to it and let them develop their effect locally and highly effectively with the help of external energy sources such as light and ultrasonic waves. The DDS will be useful in curing tumor cells without surgery. *(Fiscal 2007-2009)*

***R&D on Molecular Imaging Equipment for Malignant Tumor Therapy**

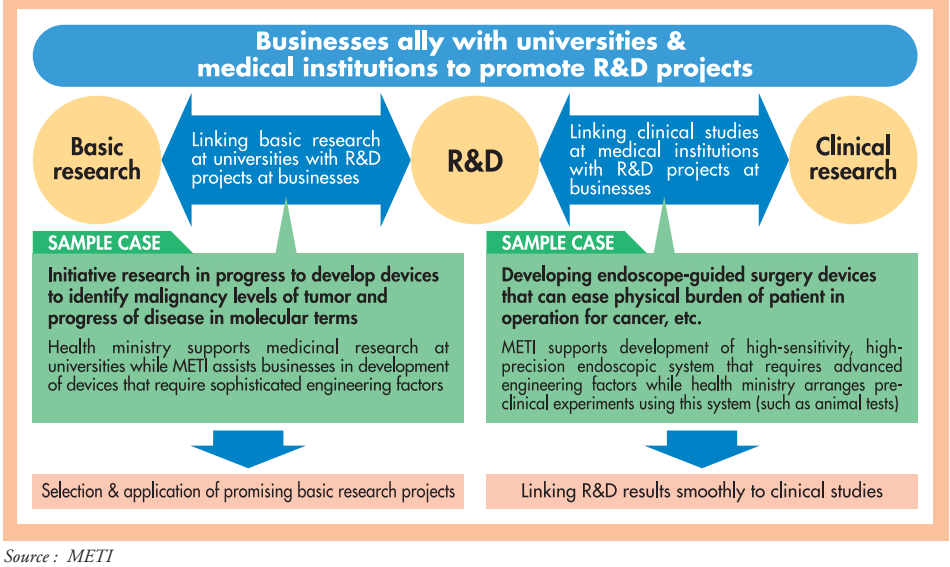
This is an imaging device that can visualize disease-specific changes – including those at a molecular level – that may occur in a patient's biological cells. The images obtained will be of high sensitivity and precision, making it possible to diagnose the nature of those changes at an extremely early stage in their development. *(Fiscal 2005-2009)*

***R&D on Regenerative Medical Technology**

The project is aimed to develop a process that can regenerate and produce cardiac muscle from a patient's own cells. Such a process can be useful in providing graft treatment to a patient with ischemic cardiac disease and dilative cardiomyopathy. *(Fiscal 2005-2009)*

There are some other projects under consideration. Among them is one aimed to forge a system that can make it easier for smaller enterprises with high technical capability to venture into the medical device business. Unlike drugs and medicines, medical instruments and devices are wide-ranging in variety. Their development requires a broad range of technologies. Japan has numerous back-street factories that employ only a handful of workers but boast one of the world's highest engineering skills. Their ingenious technologies of shop-floor production

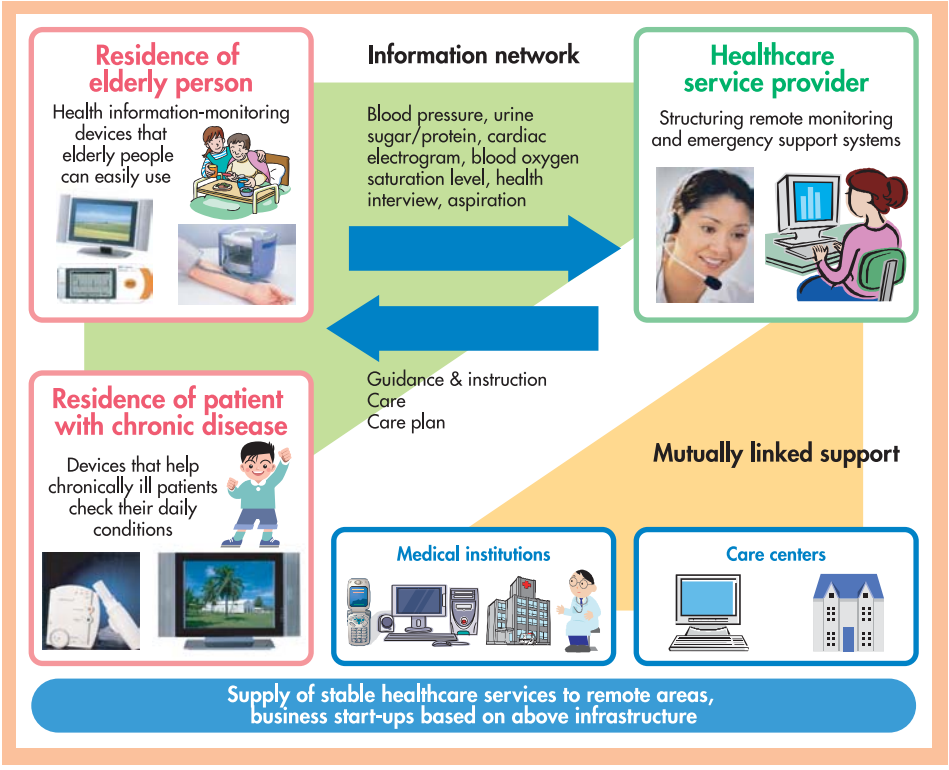
CHART 1
R&D on innovative medical devices



Source : METI

CHART 2

Demonstration project on regional health-monitoring system



Source : METI

(monozukuri) can be put together to create world-beating medical devices. In reality, however, it is not that easy. Production of medical equipment is generally considered a business that involves high risks. In fact, newcomers find it hard to enter the market, where necessary materials and components are not readily available. METI has been looking into the possibility of devising a system that can make market entry by smaller businesses easier.

(2) Medical information

Better use of medical information can allow clinics and hospitals to provide efficient and quality medical services within the framework of limited budgets. In particular, telemedical consultation services will play an important role in the treatment of elderly people and patients with chronic diseases (such as hypertension and diabetes) who live in remote areas with few medical institutions. Such services can give them greater convenience as it eases their need for hospital visits. METI is preparing to launch in fiscal 2009 a model project aimed to build and demonstrate a system to regularly monitor the health of residents in remote areas.

People can get quality medical and health services befitting their needs if they collect and keep a personal health record (PHR), such as treatment and health checkup information, throughout their lifetime and provide it to medical and health service institutions whenever necessary. METI has been carrying out since fiscal 2008 a three-year model project to provide individuals with tailor-made disease prevention and health enhancement programs based on their PHRs.

The project specifically covers four cities across the country – Urasoe in Okinawa Prefecture, Osaka in Osaka Prefecture, Kashiwa in Chiba Prefecture and Takamatsu in Kagawa Prefecture. In each city, services are offered to citizens by a consortium made up of the municipal government, medical institutions and health service providers.

There has been a spate of cases where hospitals have refused to accept critical-care patients in their perinatal period for varied reasons. This has become a major social issue. METI has joined with the health ministry in launching a feasibility study on an information and communication system that can help medical institutions readily accept such patients. A prototype system is being developed, with a model demonstration project set to be started in fiscal 2009.

3. Policy on Assistive Device Industry

The market for assistive devices will grow in size in keeping with the continued aging of Japan's population. Quality and reliable devices that everyone can easily use will be in increasing need. METI has linked up with the New Energy & Industrial Technology Development Organization (NEDO) to subsidize the development and commercialization of devices based on innovative and imaginative technologies. METI also provides information obtained from research and analysis of technological developments and user needs to manufacturers of assistive devices who are mostly small- and medium-sized enterprises.

As to future trends of assistive devices, top priority needs to be given to those useful in the care of the elderly by the elderly. In a growing number of cases, aged people will be engaged in nursing care for the elderly. This will create greater demand for products that can fully meet the needs of those who take care. Secondly, there will be a fresh need for devices that can be useful in this information-oriented society. Up until now, primary demand for assistive devices has centered on those which support basic actions such as wheelchairs and lifts. Today, personal computers are essential tools to get information, leaving in greater demand information-related devices such as those which make computer access easier. These may include devices with braille input and voice output functions. Furthermore, manufacturers may be able to dig up fresh demand by developing new products in closer cooperation with care facilities, rehabilitation centers and assistive device-leasing firms that have good knowledge of market needs.

Meanwhile, major accidents involving assistive devices have been increasing in number of late. Many of the victims in these accidents are elderly persons. Japan's pharmaceutical affairs law provides rules that govern medical equipment but sets no regulations applicable to assistive devices. Manufacturers and importers are primarily held responsible for the quality and safety of such devices. METI is preparing to work out JIS-based norms to enhance the safety of assistive devices. JS

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