Make Medical Ventures a Driving Force for Innovation!

"From Regulation To Development" "From Cautious To Speedy" "From Macro To Micro"

(Summary)

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The Advisory Panel for Fostering Medical Ventures

Ministry of Health, Labour and Welfare Japan

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Introduction

This summarizes the report by the Advisory Panel for Fostering Medical Ventures, a private round table to the Minister of Health, Labour and Welfare of Japan, first convened in December 2015. This report, delivered in July 2016, serves as a basic guideline for the development of specific policies to promote medical innovation by the Ministry of Health, Labour and Welfare of Japan (MHLW).

1. Why do we need to foster medical ventures[1]?

Globally, the medical field is a massive growth market, and Japan, that boasts high world-class level of its seeds created by universities and research institutes, has the potential to assume a leadership position in the medical field in Asia.

As the Japanese population continues to age and further decreases, it is extremely difficult and challenging to create a sustainable healthcare system and maintain a sizable working population, yet providing an opportunity with great potential.

Innovation-creating engines are shifting from large established corporations to new ventures in the United States and Europe,

Conversely, while Japan has outstanding basic research by academics and excellent manufacturing technologies of small & medium-sized companies, Japan's superior position in this area has not been fully taken advantage of yet.

It is becoming increasingly essential that these "seeds" created by Japanese domestic academia should be effectively incubated toward practical implementation and industrialization both domestically and internationally. Therefore, it is crucial to foster entrepreneurship and innovation in this medical field.

[1] The word "medical ventures" in this report means venture companies which manufacture drugs, medical devices, or cellular and tissue-based products.

Medical ventures in Japan have the following characteristics:

1) High Scientific/Technological level and Development Risk

The success rate of medical product development is said to be approximately 30,000:1, and innovation in the medical field requires considerably advanced scientific and technical levels, and at the same time, these have high risks.

2) Significant Length of Time and Amount of Capital Required for Approval

Developing medical products requires at least ten years from initial discovery of the "seed" to approval. Also, massive amounts of capital are required.

3) Understanding and Responding to Regulations Concerning to Medical Care, Pharmaceuticals, and Public Insurance

From the discovery of scientific seeds to medical products development and to their practical implementation, sufficient understanding of the regulations pertaining to medical care, pharmaceuticals, and public insurance is essential at each stage. At times, these can serve as barriers to entry.

4) Difficulty in Recruiting Highly Skilled Personnel

It can be costly and time-consuming to develop personnel who are familiar with the characteristics of the medical field, and can manage the business as described above.

The United States occupies approximately 40% of the global medical products market, and Japan no more than 10%. This signifies a major difference in investment efficiency, and necessitates effective policies with impact that will overcome these handicaps. Also, this demonstrates the great significance of positioning development from the global market perspective, not just the Japanese domestic one.

Japan's strengths and weaknesses pertaining to medical ventures are summarized as follows:

＜Strengths＞	
1) High-Quality "Seeds"	The "seeds" created by universities and research institutions stand highly evaluated in the world, and are not inferior to those of the United States and Europe.
2) Diffusion of Clinical Research	Unlike in Europe and the United States, clinical research is routinely conducted at hospitals in Japan.
3) Excellent Manufacturing Technology	Including Japan's skillful small & medium-sized companies, Japan has superb craftsmanship technology.
4) Speedy Approval Process	The approval process for pharmaceuticals is being further expedited. In particular, for products such as regenerative medicine, Japan's newly developed approval process is faster than those in Europe and the United States.
＜Weaknesses＞	
1) Personnel Shortages and Low Personal Mobility	Japan has few medical venture entrepreneurs, and securing the personnel needed for such ventures is also difficult.
2) Limited Capital Support and Incentives for Ventures	Investment in Japanese medical ventures tends to be cautious. Financial support for ventures by government and foundations is also weak. Additionally, unlike European and American large enterprises, there are few cases of the products developed by ventures acquired at substantial valuations.
3) Weak International Connections and Exchanges	There is little international human and financial exchange (both inbound and outbound), and connections are weak.
4) Regulations and Systems Unfavorable to Ventures	Many systems pertaining to medical care were created with large corporations in mind, and are difficult to engage from the venture perspective.
5) Lack of Model Cases	Japanese medical ventures are not particularly active yet, have a limited impact, and model cases are still scarce.

2. Toward the Promotion of Medical Ventures in Japan

(1) The Goals and Vision of Fostering Medical Ventures

The goals for fostering medical ventures are as follows.

- Contribute to health and medical developments in Japan and the world.
- Contribute to Japan's economic growth.

The vision brought forth by these goals is as follows:

- Center of Innovation

  In terms of predictability, transparency, and speed, we will aspire to become the nation with the world's best business environment. This intent is for developing an open innovation center, not a closed-off one limited to Japan.
- Virtuous Cycles

  Outstanding research "seeds" are commercialized as ventures and released into the world. High growth ventures flourish. The number of large companies that develop through collaboration, or acquire venture companies, will increase. A virtuous cycle is born where innovation becomes the driving force by these ventures, and the process will become highly accelerated.

(2) The "Three Principles" and "Three Pillars" of Venture Promotion Policy

Policies for the promotion of medical ventures require endeavors that are aligned with the following "Three Principles (Paradigm Shift)" and "Three Pillars."

"Three Principles"

i. "From Regulation To Development"

MHLW not only aims to ensure that companies comply strictly with regulations, but also aims for optimal regulation while recognizing that proper regulation is the foundation for supporting the sound development of an industry. MHLW must radically change its viewpoint to one that understands the characteristics and potential of new enterprises and ventures, supports and cultivates these endeavors, and promotes growth.

ii. "From Cautious To Speedy"

Business success mandates a speed that does not let opportunities slip by. This is especially true for ventures, which exist to take risks in creating businesses and products that have yet to be established. Venture promotion requires endeavors with a sense of urgency.

iii. “From Macro To Micro”

Ventures are often targeted to seeds that do not fit into a particular model. A variety of policies must be developed from a micro-standpoint suited to specific characteristics so that corporations, such as ventures, can fully display their unique traits.

“Three Pillars”

In order to realize a paradigm shift addressing these three principles, venture promotion measures that surpass existing frameworks will be implemented, fostering a medical venture ecosystem.

i. “Creating a System that Nurtures Ecosystems”

Nurturing a venture ecosystem requires creating a system allowing swifter approval and insurance listing based on regulatory science, according to the needs of each venture’s growth stage.

ii. “Creating a Space for Developing and Interacting with Personnel that will Create the Ecosystem”

In order to lay the groundwork for the stimulation of innovation, it is important to create positive spirals by linking various stakeholders involved with ventures.

People are the lifeblood of an ecosystem, so attracting and securing personnel to promote exchange and mobility, and further personnel development is required. Furthermore, for the future, overseas connections and growth and developments into new areas will be required.

iii. “Creating an “All MHLW” Venture Support System”

We should establish a system that will plan, implement, and monitor medical venture promotion policies, create an organization to support ventures at key institutions, and to enhance endeavors to continuously support and promote ventures.

(3) Specific Initiatives

1. Creating a System to Nurture Ecosystems

<Fast Break Scheme (Accelerated Approval for Innovative Medical Devices)>
A system for accelerated approval of innovative medical devices should be created, minimizing the burden on pre-market clinical trials and expanding after-market studies.

<Examination of the System for Drug and Materials Prices>

a. Creation of a Drug Price System to Evaluates Innovation

1) Drug prices should be evaluated, taking into account its characteristics based on studies on actual conditions, including medical ventures' cost structures.

2) A working group of the Central Social Insurance Medical Council should examine pricing of innovative products expected to be effective for critical conditions which existing treatments have limited impact on. Since the current pricing process does not adequately assess innovation, long-term cost-effectiveness should be considered and innovation should be additionally counted on pricing.

b. Exemptions from Approval Examinations/Consultation Fees and Enhancement of Development Subsidies

Along with expanding exemptions from approval examinations and consultation fees for Pharmaceuticals and Medical Devices Agency (PMDA) in medical device ventures that are not profitable to include medical ventures of cellular and tissue-based products, development assistance should be increased for "orphan disorders."

<Post-Market Support>

a. Promotion of PMS Utilizing Electronic Clinical Data

In PMDA, the promotion of post-market surveillance (PMS) based on regulatory science utilizing electronic clinical data is essential. Therefore, the promotion of enterprises to create databases of medical data (MID-NET enterprises) and clinical information networks (CIN) will be required.

b. Promoting the Development of a Registry for Each Disease in CIN

For venture companies, starting development from niche disease fields such as intractable diseases and rare diseases is the secret to success, and in order to support these, it will be necessary to advance the development of disease-specific registries in CIN.

c. Financial Support

For PMS, financial support, with combination of financial support in a development stage, will be required to meet financing needs.

<Overseas Development Assistance and Export Promotion>

a. Support for Overseas Development via International Pharmaceutical Consultation

Under the coordination of the "Venture Support Strategy Office (Provisional Name, Details Below)" to be established in MHLW, information acquired via by MHLW or PMDA will be provided regarding overseas pharmaceutical regulation, and should support overseas development.

b. Promotion of Research and Development Targeting the Creation of Evidence According to Needs and Conditions

In order to receive research and development suitable for local specs for developing countries,

and to obtain regulatory on-site approval, research and development aimed at the construction of evidence considering race and environment, etc. should be promoted. Even in the domestic unapproved stage, we should also support information sharing, experience sharing, etc. as one strategy for ventures to make clinical trials and sales advances in this market.

<Medical Venture Investment Promotion>
The relevant ministries and agencies should cooperate to improve the tax system and accounting standards for promoting investment in medical ventures.

2. Developing Personnel Who Will Construct the Ecosystem and Creating a Space for Exchange

<Implement Activities that Match Key Personnel>
For medical ventures, obtaining enterprise/development partnerships with large pharmaceutical and medical device companies is a matter of life and death, and is extremely important.

MHLW must take the lead and match individual executives at potential enterprises/development partners such as large corporations with executives at medical ventures. Aside from individual introductions, MHLW should attempt to host supporting events and contests with prizes. Also, MHLW must promote the creation and development of ecosystems that also include products and services through combinations with information technology.

<Securing and Introducing Mentor Human Resources>
In order to secure mentors, a domestic and international registry should be created of persons who possess vast knowledge (intellectual property, pharmaceuticals, insurance, management, etc.) relating to issues that occur at the stages from the development of to the practical implementation of pharmaceuticals and medical devices, and persons with practical experience leading up to expansion and diffusion in global markets. These persons should be matched according to the needs of the respective ventures. Also, ventures should be educated on how to accept personnel. Furthermore, attempts should be made to create a voluntary community of mentors and ventures.

<Developing Judgment Personnel through Personnel Mobility>
In Japan, a lack of "judgment" capable of serving as a bridge between medical ventures and financial entities is a problem. To overcome this problem, a diverse career development environment should be created by MHLW, targeting career veterans through personnel exchanges between financial institutions and cutting-edge global ventures. By promoting such personnel exchanges, in addition to enhancing the market value of these people, it will encourage financial entities to evaluate specialized areas.

<Development from the Young Generation and International Personnel>
Education pertaining to medical and health care technology should be incorporated into high

school, technical colleges, and undergraduate university engineering departments. Also, the development of international personnel in Japan (dispatch to overseas agencies and corporations, study abroad, etc.) and the utilization of overseas personnel should be actively implemented.

<Creating an Environment that Fosters the Creation of Intellectual Property and Corporations>

In health care areas that target researchers, training programs should be created pertaining to enterprise strategy, from the protection of intellectual property and non-clinical testing up to POC acquisition via clinical testing, and should be utilized when applying to research enterprises.

<Efforts to Create Overseas Links>

a. International Perspectives Utilizing Overseas Personnel and Development of Personnel

We will take efforts to engage in information exchanges and joint operations with overseas medical and health care research institutes, MHLW, and private-sector organizations. We will promptly establish partnerships between key institutes and organizations. Also, we will promote the establishment of international joint operations for overseas medical and healthcare startups.

b. Creation of a Japanese “Patent Box”

Allowing for the “Patent Box” in Japan would assumedly be beneficial, because corporations developing advanced technology from overseas can register them in Japan. This would be effective not just for developing domestic companies, but also for inviting personnel from overseas.

<Expansion into New Fields>

The potential of new fields, such as frameworks surpassing existing ones for pharmaceuticals and medical devices, and innovations through new mergers of pharmaceuticals, medical devices, ICT and services should be pursued and incorporated into the ecosystem.

This is to encourage medical ventures to actively accept the challenges of research and development fields previously untapped, for example, promoting “Assessment Method Research Support” for medical ventures engaged in innovative medical product and device research and development.

3. Creation of an “All MHLW” Venture Support System

<Establishment of a Venture Support Structure at the MHLW, PMDA and Core Clinical Research Hospitals>

a. Establish a new Venture Support Strategy Office

First, within one year a Venture Support Strategy Office (VSOO) should be established within MHLW to act as the “control tower” for planning, implementing, and monitoring policies that

promote medical ventures. VSOO must coordinate with the relevant government agencies and departments, and with PMDA. VSOO should provide comprehensive consultation to new ventures as the gate for entrepreneurs and researchers.

Second, PMDA should also establish an office to support the practical application of the "seeds" held by small-scale enterprises, including medical ventures, within one year.

Third, a venture support department should be established within core clinical research hospitals that are closest to the front lines of innovation, and a finer nationwide support structure should be constructed.

b. Construct a PDCA Cycle for Venture Support Policies

It will be necessary to establish a Plan-Do-Check-Act (PDCA) cycle to verify the effectiveness of medical ventures support measures, and lead to improvement. Also, for the initiatives presented in this report, in addition to creating opportunities for discussion with the relevant persons in industry, academia, and government, the implementation status of this report should be checked annually, and as necessary, routed through a PDCA cycle where a new action plan is created.