



Medical Ventures as a Driving Force for the Success in Innovation

July 29, 2016

Report of the Advisory Panel for Promotion of Medical Ventures (Summary)

Innovation is a **key trigger** for **Japan's economic growth** in the future. A **venture company** is a **driving force** which holds the key for success in **innovation**. And, progress in drugs and medical devices is an **“investment for the future.”**

This report is compiled to provide **guiding principles for MHLW's policy** for medical ventures.

※ Medical ventures = Venture companies for drugs, medical devices, and cellular and tissue-based products

I. Importance and necessity of promotion of medical ventures

◆ There is a very high growth potential in healthcare.

- Healthcare is a huge growing market across the world.
- There is a need to respond to issues, such as, the extension of healthy life expectancy and building of a sustainable healthcare system, within the country.

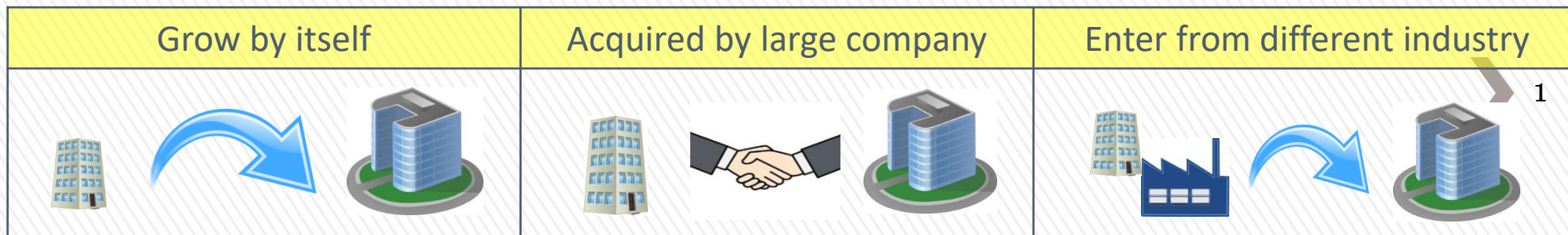
◆ Venture companies play a central part in the innovation of drugs and medical devices in the future.

- While specialization proceeds in mega pharma in the US & EU, many new drugs are being developed by venture companies.
- Cutting-edge technologies used in different fields are increasingly put to use for the development of medical devices, etc.
- While our basic research and manufacturing technology are advanced, medical ventures play limited roles in Japan.

◆ Promotion of medical ventures is an urgent issue for Japan.

- In view of trends in drug development, widespread use of generic drugs, and others, promotion of medical ventures is a pressing matter.

◆ Three types of Medical ventures



II. Issues for promotion of Medical ventures

Characteristics of medical ventures

The following characteristics of Medical ventures present a host of challenges

- ① Medical innovation requires a high level of science and technology and accompanies high risks for development.
- ② Development and approval take an extremely long time and require an enormous amount of money.
- ③ Regulations on medicines, pharmaceuticals and public insurance may become barriers to entry. It is important to have a good understanding on them.
- ④ Training new entrepreneurs requires a long time and costs.

Japan's strengths & weaknesses

For Japanese medical ventures to improve their capital efficiency, they should look into the possibility of expanding into foreign markets

Advantages

- There are many world-class seeds in universities and research institutions.
- Clinical research is widely practiced in hospitals.
- Many small & medium-sized companies have advanced manufacturing technologies.
- Approval process of drugs & medical devices is accelerated (e.g. regenerative medical products)

Disadvantages

- There are few entrepreneurs, and it is difficult to secure human resources for ventures.
- Venture capital investment is scarce, and funding support is weak.
- Human & capital networks with foreign countries are weak.
- Venture companies are not considered in the medical system and others.
- Successful cases of medical ventures are very few.

If strengths can be utilized and weaknesses can be overcome, the importance of promoting medical ventures and the potential of their growth are great.

III. Promotion measures for medical ventures

“The Goal”

Medical ventures lead innovation

Enhancement of healthcare standards
in Japan & the world

Contribution to economic growth in Japan

“The Vision”

To be the center of innovation

Japan will become a country with the best
business environment in the world.

To produce a virtuous cycle of innovation

Japan will accelerate a virtuous cycle of
innovation (R&D ↔ Business).

◆ “Three principles” & “Three pillars” of promotion measures

<Three principles (paradigm shift)>

From Regulation To Development

Proper regulation from the venture business point of view
Support from MHLW

From Cautious To Speedy

Promotion measures with a sense of urgency

From Macro To Micro

Provision of support according to the
characteristics of each company

<Three pillars>

To establish
systems that
foster
“ecosystems” of
medical
ventures

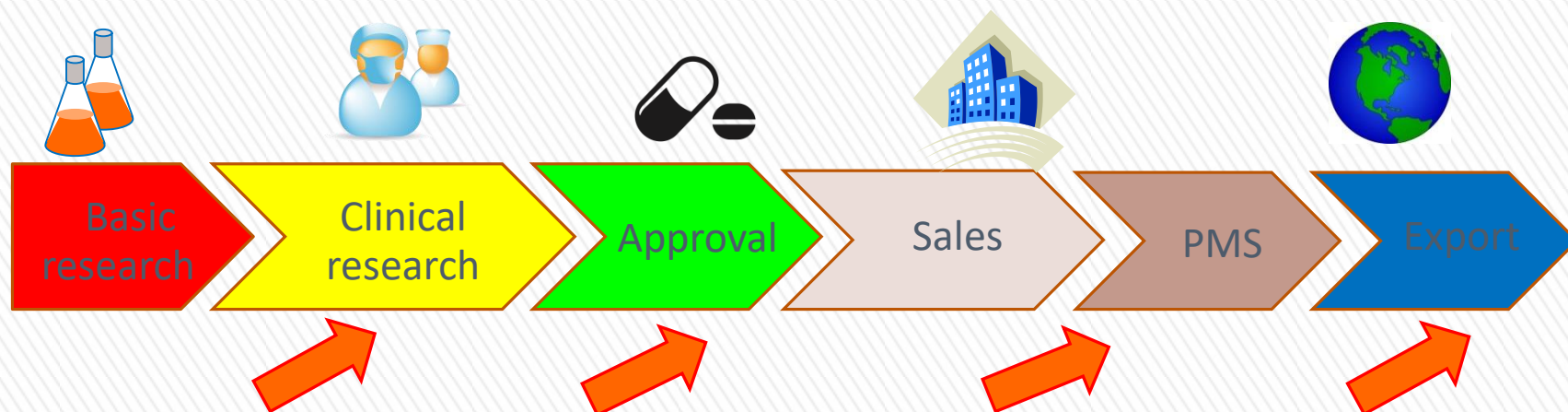
To develop
human
resources for
“ecosystems”
and provide
places for
interaction

To build a
support
system of
“All-MHLW”
for ventures

◆ Specific measures taken in line with “three pillars”

①

◁ First pillar - Establishment of systems that foster “ecosystems” of medical ventures ▷



◆ New system for earlier approval of innovative medical devices

◆ New consultation system under collaboration between pharmaceutical affairs and public insurance

◆ Review of the drug & medical device pricing system (for public insurance)

- Proper pricing corresponding to the characteristics of venture companies
- Proper pricing of innovation where price premiums have failed to cover adequately
- Proper pricing for high costs involved in R&Ds and production

◆ Support for post-marketing surveillance (PMS)

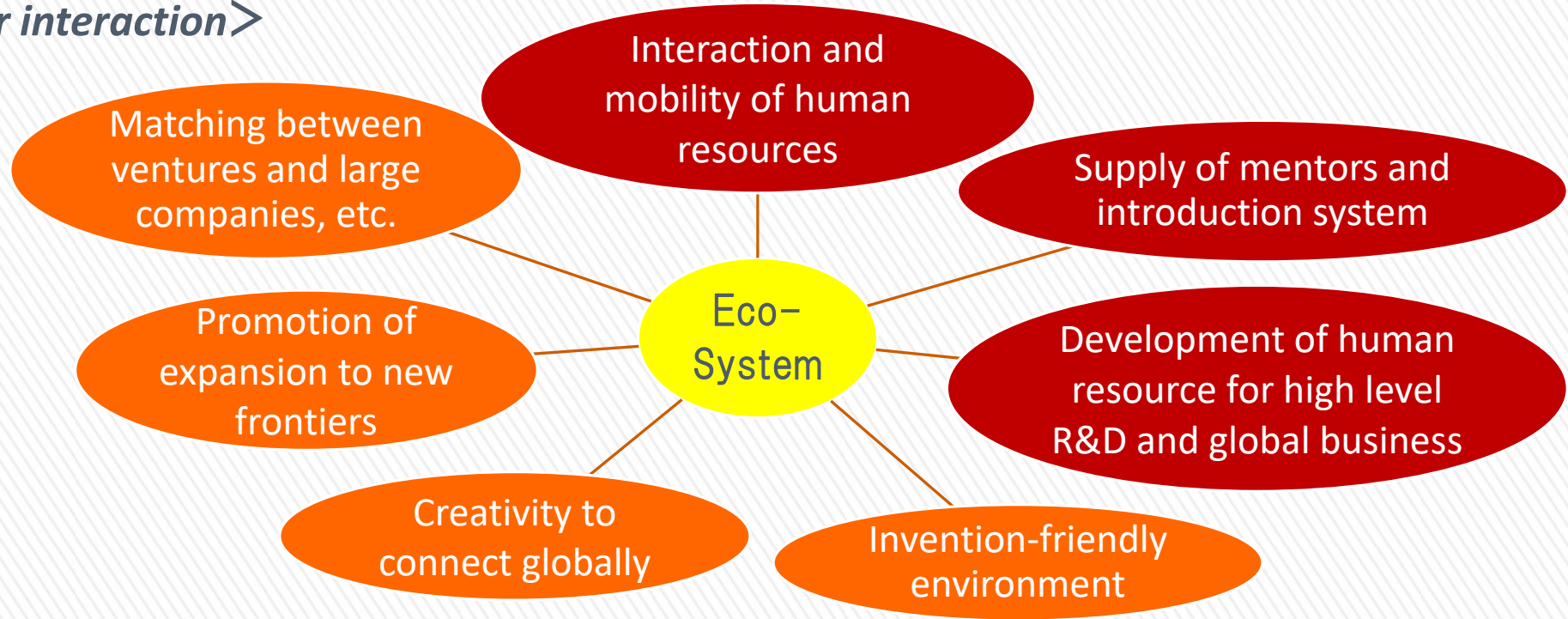
- Promotion of PMS that utilizes IT clinical data, etc.
- Improvement of the disease registry for “Clinical Innovation Network”
- Reduction of financial costs involved in PMS

◆ Support for global businesses

- Establishment of international consultation system for pharmaceutical affairs
- Build-up of clinical evidence based on local needs, etc.

◆ Specific measures taken in line with “three pillars” ②

<Second pillar – Development of human resources for “ecosystems” and provide places for interaction>



<Third pillar - Organizational support by “all MHLW”>

