International Regulatory Science Symposium

2014 Summer Fest Kickoff

“Collaborate, Innovate, Globalize”

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Japan Update Introduction

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Canada

France

Male

Netherlands

UK

JAPAN

Dr Mike Ferris, Novartis, 2009 Lecture at Chiba Univ.
Japan’s Ageing Population

- **2005 (Actual)**
  - Total Population: 127.77 million
  - 75 year olds: 1,164 (9%)
  - 65 - 74 year olds: 1,412 (11%)
  - 20 - 64 year olds: 7,783 (61%)
  - - 19 year olds: 2,418 (19%)

- **2030**
  - Total Population: 115.22 million
  - 75 year olds: 2,266 (20%)
  - 65 - 74 year olds: 1,401 (12%)
  - 20 - 64 year olds: 6,305 (55%)
  - - 19 year olds: 1,550 (13%)

- **2055**
  - Total Population: 89.93 million
  - 75 year olds: 2,387 (27%)
  - 65 - 74 year olds: 1,260 (14%)
  - 20 - 64 year olds: 4,290 (48%)
  - - 19 year olds: 1,057 (12%)

Population of 65 year olds and above
1 person
Population of 20 - 64 year olds
3.0 persons

Population of 19 year olds
1 person

Variant due to the trend in the number of births for the future
Environment
Rapidly aging population; 65 years & over

Share of people with ages 65 years and over is expected to grow rapidly in Japan.

Lifestyle Diseases
Dr Mike Ferris,
Chiba University
June 2009
Change of Japan’s Family Income

△: percentage of decrease

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<tr>
<th>Year</th>
<th>Income Million Yen</th>
<th>Change</th>
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<td>2001</td>
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<td>2007</td>
<td>2.4</td>
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<tr>
<td>2008</td>
<td>1.0</td>
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International comparison of medical services in terms of medical profession in 2005

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<td>2.4</td>
<td>233.0 (2002)</td>
<td>7.9 (2002)</td>
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出典：OECD Health Data 2007
A few characteristics of Japan’s medical service/system and people

• Facility intensive investment (cf. CT scan, MRI etc.) and associated less professional manpower situation
• Firm prediction of becoming a less rich society because of rapidly maturing population
• Questions:
  – How could we accommodate increase of demands/needs for medical services in the era of rapidly aging society
  – How could we attain optimum use of medical and medicinal resources
Drug development: conditions

• Affordability and accessibility of medicines
  – supported by sustainable new drug development model in the era of life science, human genomics and longevity

• Requirement for a new drug which affects on our current medical/medicinal system and services
  – introduction of health technology assessment/outcome research
  – development and operation of nation-wide scale medical data base
Is it an emergency bypass? : Acceptance of off-label reimbursement

- Recent movement of health insurance scheme
  - Reimbursement of off-label use
  - 2007  47 cases were recognized
    - rare cancer and tumor
  - 2009  33 cases
    - rare cancer and tumor
  - 2011  80 cases
    - with rare central nervous system drugs
Step out into discussion from other angles and even forbidden ground

- A symposium of Japan Gerontology Society issued a draft guidelines suggesting an artificial water and nutrition supply could be refrained or interrupted when the patient’s living will or spirit does not entertain such intervention, even such intervention may invited some prolongation of life.

- “Now the time has come for us to seriously think about how to die.” (At General Assembly of Public Health Society)
Pharmaceutical Industry, regulation and clinical development

• What is the structural impediment for promotion of clinical trials and drug development?
Historical Background

- Historically, regulatory interest is placed in quality side, such as eradication of misbranded and/or counterfeit drugs by enforcement of law and inspection.

- Only a limited attention on promotion side of concerned industry, as well as encouragement of new drug R&D had been pied in 20th century.
Recent changes

- Significant changes in Pharmaceutical and Medical Device Agency into a supporter of new drug/medical device development and registration
- Amendment of Pharmaceutical Affairs Law will be implemented soon
  - regenerative medicine, application of iPS cells
  - Medical devices research and evaluation
  - Involvement of patient/people’s responsibilities in terms of safe and effective drug use
Amendment of Pharmaceutical Affairs Law
View points of amendment of PAL

• Reconsideration on purpose and benefit of Pharmaceutical Affairs Law
• Message of the necessity of taking necessary measures for preventing injuries in terms of public health and hygiene and avoiding enlargement of such accident
• Message of the each respective responsibilities for preventing “Yakugai” among all stakeholders including people and patients.
Responsibilities of stakeholders

• The Government shoulders the responsibilities of establishment and implementation of necessary measures for attainment of drug/medical device safety, efficacy and quality.

• Provincial governments shoulder the responsibilities of, through adequate collaboration and role sharing with the Government, establishment and implementation of necessary measures for attainment of drug/medical device safety, efficacy and quality.
Responsibilities of stakeholders (2)

• Medical care providers such as medical doctors, dentists, pharmacists, nurses and other health related professionals are supposed to provide people with necessary information for adequate use of drugs and medical devices.

• Comments/requests such as necessity of introducing the responsibility for collection and use of such information and also establishment of a reporting system from patients were raised and recorded.
Responsibilities of stakeholders (3)

• The drug and medical device related companies shoulder the responsibilities of taking necessary measures for attainment of drug/medical device safety, efficacy and quality.

• People of Japan are supposed to shoulder significant role for the establishment of drug quality, safety and efficacy through improvement of their own understandings and knowledge on drug quality, safety and efficacy.
Reinforcement of Safety Measures

– Reinforcement of PMS and establishment of risk management system/RMP
– Reinforcement of ADR collection, management and analysis
– Reconsideration of legal status of package insert
– Improvement of recall system
– Promotion of risk communication with patients
– Reinforcement of GMP inspection
– and many other safety related considerations
Rapid and more timely approval of urgently needed drugs/medical devices
– Support system for the development of drugs/medical devices for orphan diseases
– Improvement of patients’ accessibility to unapproved drug with serious medical needs
– Provision of right for a fast track of evaluation
– Projection of compassionate use of drugs
– Creation of a new system for uniquely fitted for medical devices
– Preparation for regenerative medicines
– Preparation for clinical trials and drug inspection
Concept of Self-medication

- Switch OTC of Epadel (eicosapentaenoic acid)
- A number of “Metabolic syndrome” patients come up to 22 million.
- Promotion of self-medication and Switch OTCs
- Recent open up of self clinical check on his/her own blood at retailers with adequate facility
Imprecations

• Health and Medical issues: Japan cannot postpone our facing issues any more to the future

• Break through could only be seen in further development/application of new and improved science and technology in association with improvement of medical service system
Conclusion

- Awareness of cost effectiveness at the treatment of patient and introduction of a concept like “just appropriate amount” would be a key factor.
- Employment of “regulatory science” for benefiting from such scientific progress with the best productive and safest way to the industries and eventually to the people.
- A new paradigm could be expected by introduction of amendment of PAL.
Thank you for your attention.

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감사합니다

ありがとうございました