Progress of “Pharmaceutical Industry Vision”
"Action Plan for Reinforcement of Global Competition"

October 25, 2004
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Progress of “Pharmaceutical Industry Vision”

August 2002  Release of “Pharmaceutical Industry Vision”

December Establishment of Headquarters for Promotion of Pharmaceutical and Medical Device Industry Policy (cross-department organization with MHLW Vice-Minister as Director-General)

April 2004 Summary and release of progress of Action Plan etc.

June Holding discussion meetings to hear views of pharmaceutical industry stakeholders on overall pharmaceutical industry policies including progress of the Action Plan
Framework of Action Plans
Supportive Measures in 4 Stages

Research
- Disease-related proteins analysis projects
- Establishment of MHLW version of TLO
- Expansion of tax incentives for R&D

Development
- Development of “3-Year Plan for National Revitalization of Clinical Trials”
  - Creation of “Large-Scale Clinical Trial Network”

Production
- Organizational merger of OPSR and PMDEC

Marketing
- Medium-to-long range review of drug pricing and drug benefits system
Disease-related Protein Analysis Project

- Implement large-scale improvement of infrastructure under the framework of academic, industrial and governmental coordination with a view to carrying out an analysis of functions of disease-related proteins that will provide important clues for discovery of research targets for new drugs

- Program accelerated through provision in fiscal 2002 supplemental budget (4.3 billion yen)
  - Fiscal 2003 initial budget allocation: 500 million yen
  - Fiscal 2004 initial budget allocation: 660 million yen
  - Fiscal 2005 initial budget request: 660 million yen
Creation of an MHLW version of a TLO

- It is important to make it a reality by utilizing the results of basic research obtained by national research organizations.

- July 1, 2003 Japan Health Sciences Foundation certified as an MHLW version of a technology licensing organization (TLO)
The past taxation system in which a fixed ratio corresponding to an increased portion of R&D expense from the preceding year was deducted from taxes has been changed into a taxation system that allows businesses to deduct 8 to 10% (10 to 12% in the first three years) of total R&D expenses from taxes. (since FY2003)

- Deduction rate to increase according to percentage of R&D expenses.
Form a large-scale clinical trial network
- Over the next 3 years, create a large-scale clinical trial network of national advanced medical centers, specific function hospitals, and clinical research designated hospitals for each disease group for each disease category
  Fiscal 2003 budget 850 million yen, Fiscal 2004 budget 1.1 billion yen, initial budget request for fiscal 2004 2.2 billion yen

Improve clinical trial systems at medical institutions
- Train a total of 5,000 clinical research coordinators (CRC) by fiscal 2005
- Improve understanding and provide education on GCP

Establishment of comprehensive advisory services from clinical trial through to application for regulatory approval
- Install inside the Pharmaceutical and Medical Device Organization (PMDO), which is an independent administrative corporation to be launched in 2004 as a new review body for drugs and medical devices, a consultation desk concerning the procedures necessary for clinical trial designs to regulatory approval.

Facilitation of physician-initiated clinical trials
- Facilitate clinical trials initiated by physicians as well as by companies
Drafting of Ethical Guidelines for Clinical Research

【Objective】
Proper promotion of clinical research

【Scope of Application】
Covers individuals in medical research conducted for the purpose of finding disease prevention methods in healthcare, improving diagnostic techniques and therapeutic methods, understanding the causes and pathology of diseases and improving patient QOL (including research on human-derived materials and data where the individual is identifiable)

【Contents】
- Basic principles to be complied with by researchers (dignity of individual, respect for human rights etc.)
- Duties etc. of head of clinical research institution
- Duties, membership, duty of confidentiality of members etc. of Ethical Review Board
- Procedures for informed consent

【Effective】
July 30 2003 (Notification made on July 16)
Consolidation of Drug Organization (Kiko) and Pharmaceuticals and Medical Devices Evaluation Center, etc.

- Consolidate review division of the current Kiko and Evaluation Center
- Centralization of review and quantitative and qualitative expansion of staff in charge of review in order to:
  - “Speed up” and “Improve quality” of review
Discussion of medium-to-long range status of drug pricing and drug benefits

• MHLW also participating in industry Study Group to harmonize with the global competitiveness of the drug industry, and collecting data and exchanging views etc. on the medium-to-long range status of drug pricing and drug benefits

Status of drug pricing and drug benefits to be discussed with reference to the basic policy on the health insurance system and the medical fees system
Gist of Views Expressed at Discussion Meetings on Promotion of Pharmaceutical Industry Policy (June 2004)

- Certain degree of acclaim for implementation process of Action Plan

- Critical comments on progress of some of the individual items

  In particular:
  - Promotion of clinical trials environment
  - Acceleration of reviews
  - Fair reflection of technological innovation in drug prices
Further Implementation of Pharmaceutical Industry Vision

- Headquarters Secretariat to review current status of each task in light of views expressed at discussion meetings
  - Secure necessary budget provision and promote systemic revisions

- Compilation and release of progress reports as appropriate, and continued dialogue between the industry and the government

- Viewpoint of patients/people
Progressive Development of the Pharmaceutical Industry

- Increasing Medical Needs
- Innovation (Genomic medicines and new business models, etc.)
- Internationally Attractive Drug Discovery Environment
- Strategic Corporate Action

- Development in Sciences
- Technological Reform
- Revitalization of Drug Research
- Reinforcement of Global Competitiveness of Industry
- National Economic Expansion
  - Increase in employment
  - New business creation

Assurance of profits and new investment in R&D Further solutions to medical needs

Creation of New Breakthrough Drugs!

Further innovation
Future Image of the Pharmaceutical Industry (in 10 Years)

The structure of a globally competitive pharmaceutical industry in 10 years, an era of worldwide "genomic drugs" and "tailor-made medicine"

- Mega-pharmas
- Specialty pharmas
- Generic pharmas
- OTC pharmas

Possible emergence of new businesses such as research-based venture firms, CRO/SMO, contract manufacturing businesses, etc.