Update in PMDA

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Outline

- To shorten and disappear drug lag
- Publication of our philosophy
- Improvement of English website
Measures and Policies to Reduce the Drug Lag
Target Setting FY 2007 ~ 2011 (5 years)

Aims: To reduce the “drug lag” by a total of 2.5 years by 2011 through 1.5 year and 1.0 year reductions respectively in the development and approval times; and to cut down the marketing lag to 500 days in line with the U.S.

Development time
Current time lag of application between Japan and US/EU: 4.3 years (median)

To reduce current time lag of application between Japan and US/EU by 1.5 years

Approval review time
Present total review time of standard products: 22 – 24 months (median)

To reduce Total TC (median) for standard products applied after FY2004 by 1.0 year

To reduce a total of 2.5 years

Enhancement of Review Process and Risk Management

Present

Clinical trial consultations etc.
Correction and addition of data
Rejection of inadequate data
Review
Safety

No consultation
Future

Clinical trial consultations on -development strategy
-Global clinical trial
-Pharmacovigilance
Review
Safety
Introduction of new risk management

I. Enhancement of CT consultation
- Conduct the review of toxicity and pharmacology etc. beforehand as a part of consultation
- Advice on development strategy at the early stage of development, clarification of review policy
- Enhanced measures for global collaborative clinical trial and state-of-the-art science and technology

II. Review with selected focuses
- Focused on essential evaluation of efficacy and safety

III. Enhancement of safety measure
- Start giving advice and instruction on pharmacovigilance from the consultation stage
Introduction of Risk Management System

- Purpose of RM System
  - PMDA will collect, compile, evaluate and manage all the safety information on new drugs from development to post approval stages to give guidance and advice to companies on PMS at early stage and in a timely manner.
  - PMDA RM System will help the life cycle management of drugs in safety aspect
    - Identification safety specification from development stage
    - Guidance and advice on designing post-approval surveys, studies and other activities at review stage
    - Evaluation and advice on outcome and problems of post-approval surveys, studies and other activities etc
  - Tentatively called ‘Product Management’

Possible Benefits of New Risk Management System

- Efficient preparation of effective PMS plan
- Consistent safety management throughout lifecycle both in PMDA and companies
- Preventing withdrawal of new drugs (at early stage)
- Completion of lifecycle of a drug
- Protection of patients especially at early stage of marketing
PMDA continues to improve the public health and safety of our nation by reviewing applications for marketing approval of pharmaceuticals and medical devices, conducting safety measures, and providing relief to people who have suffered from adverse drug reactions. We conduct our mission in accordance with the following principles:

- We pursue the development of medical science while performing our duty with greater transparency based on our mission to protect public health and the lives of our citizens.
- We will be the bridge between the patients and their wishes for faster access to safer and more effective drugs and medical devices.
- We make science-based judgments on quality, safety, and efficacy of medical products by training personnel to have the latest technical knowledge and wisdom in their field of expertise.
- We play an active role within the international community by promoting international harmonization.
- We conduct services in a way that is trusted by the public based on our experiences from the past.

Most of documents were posted in only Japanese on PMDA website. Increasing documents written in English:

- Important notifications
- PMDA review policy
- Review reports
  - First approval in the world