PMDA’s Efforts to strengthen New Drug Review
- 加快审批速度 -
- How we accelerate reviewing speed -

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Shanghai, China
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神农尝百草调查是毒还是药
Shennong used to judge the poison or the medicine by tasting various grasses.

PMDA审查医药的有效性调查安全性
PMDA examines the effectiveness of the medicine and investigates safety.
What is Drug Lag?

新药认可的延迟 是什么？
3个延迟 Three types of lag

美国 US

R&D

美国审查 US review

美国市贩 sold in US market

日本 Japan

研究开发 R&D

日本审查 Japan review

日本市贩 sold in Japan market

申请预审 lag
pre-application lag

审查延迟 lag
review lag

新药认可的延迟 Drug Lag

申请 application

认可 approval
Definition of term:

- **Pre-application lag (申請延迟)**
  - The median of the difference of application time between Japan and the U.S.

- **Review lag (审查延迟)**
  - The difference of the total review period (median) of the new drug between Japan and the U.S.

- **Drug lag (新薬認可の遅延)**
  - The sum of pre-application lag and review lag.
How can we shorten Drug Lag?

怎样做能缩短新药认可的延迟？
3个延迟的关系
The relation of three lag

新药认可的延迟
Drug Lag

申请延迟
pre-application lag

审查延迟
review lag
**Researcher:** University, research institution, etc.

New ingredients are discovered by basic research.

However, they have no funds and means to develop new drug.

**Developer:** Drug manufacture company

New drugs are developed using new ingredients.

In order to apply, it is necessary to prepare data completely.

**Reviewer:** PMDA

New drugs are reviewed only based on their application data.

Imperfect data require time for reference.

How can we shorten pre-application lag?
Researchers: University, research institution, etc.

New ingredients are discovered by basic research.

However, they have no funds and means to develop new drug.

Developers: Drug manufacture company

New drugs are developed using new ingredients.

In order to apply, it is necessary to prepare data completely.

Mr. Ando is going to explain for details.
开发者方面和审查者方面
Developer side and Reviewer side

临床试验咨询
Clinical Trial Consultation

详细高野先生说明的预定
Mr. Takano is going to explain for details.

开发者Developer: 制药企业 drug manufacture company

用新成分进行新药开发
New drugs are developed using new ingredients.

为了申请 需要完全准备资料
In order to apply, it is necessary to prepare data completely.

审查者Reviewer: 医药品及医疗器械管理机构 PMDA

根据申请 资料进行新药审查
New drugs are reviewed only based on their application data.

不完全的资料查询花费时间
Imperfect data require time for reference.
如何是不是缩短审查延迟？
How can we shorten review lag?

审查期间和工作量逆相关
Review time is inversely correlated with the output.

\[
\text{审查期间 (review time)} \propto \frac{1}{\text{工作量 (output)}}
\]

工作量 = 职员的本领 \times 职员的人数
output = staff skill \times staff size
如何是不是缩短审查延迟？
How can we shorten review lag?

职员的本领
staff skill
进修的充实 to enrich training

职员的人数
staff size
增加职员数
to increase number of personnel

人材交流的促进
to promote talented-personnel exchange
进修的充实 - 内部进修

*to enrich training – internal trainings*

- 新任者进修以外
  - other than training session for newly appointed personnel
- 新任者进修
  - training session for newly appointed personnel

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4th DIA China Annual Meeting: Collaboration and Innovation in China
May 20-23, 2012 | Shanghai, China
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### Bar Chart

- **For expert: outside lecturer**
  - FY2010
  - FY2011

- **For expert: PMDA staff as a lecturer**
  - FY2010
  - FY2011

- **General: outside lecturer**
  - FY2010
  - FY2011

- **General: PMDA staff as a lecturer**
  - FY2010
  - FY2011
进修的充实 - 海外进修参加者数

to enrich training - number of participants for overseas trainings

FY2011

FY2010

0 10 20 30

1 28

3 20

Long Term
Short Term

1 28

3 20

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How can we shorten review lag?

职员的本领 (staff skill)
进修的充实 to enrich training
人材交流的促进 to promote talented-personnel exchange

职员的人数 (staff size)
增加职员数 to increase number of personnel
PMDA职员数  PMDA Staff Size

计划人数 Planned
审查部门 Review Department
安全部门 Safety Department
总务部门 Administrative part

256 291 319 341 426 521 605 678 751


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As the Result

作为结果
新药审查期间
Review Time for New Drugs

优先审查品种  Priority Review Products

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通常品种  Standard Review Products

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<td>The number of applied items</td>
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Thank you for your attention