This is How PMDA Achieved the NDA Review Cycle Time Target
審査期間の短縮をどのように成し遂げたか

TRACK B: NDA Review Cycle Time Becoming Close to 12 Months; Aiming for Simultaneous Global NDA Approvals
審査期間12ヶ月時代：医薬品世界同時開発を目指して

Takeyuki SATO
Associate Director,
Centre for Product Evaluation
PMDA

8th DIA Japan Annual Meeting
October 28, 2011, Tokyo
Disclaimer

• The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to Drug Information Association, Inc. (“DIA”), its directors, officers, employees, volunteers, members, chapters, councils, Special Interest Area Communities or affiliates, or any organization with which the presenter is employed or affiliated.

• These PowerPoint slides are the intellectual property of the individual presenter and are protected under the copyright laws of the United States of America and other countries. Used by permission. All rights reserved. Drug Information Association, Drug Information Association Inc., DIA and DIA logo are registered trademarks. All other trademarks are the property of their respective owners.
Review Time for New Drugs (1) (Standard Review Products)

【Target (Standard Review Products)】
(1) FY2011
Total Review Time for New Drugs: 12 months (median)
- Regulatory review time: 9 months
- Applicant’s time: 3 months

(2) FY2010
Total Review Time for New Drugs: 16 months (median)
- Regulatory review time: 11 months
- Applicant’s time: 5 months

【Median Total Review Time for New Drugs (Standard Review Products)】

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of approved applications</td>
<td>53</td>
<td>53</td>
<td>92</td>
<td>92</td>
<td>—</td>
</tr>
<tr>
<td>Total review time (months)</td>
<td>20.7</td>
<td>22.0</td>
<td>19.2</td>
<td>14.7</td>
<td>16</td>
</tr>
<tr>
<td>Regulatory review time (months)</td>
<td>12.9</td>
<td>11.3</td>
<td>10.5</td>
<td>7.6</td>
<td>11</td>
</tr>
<tr>
<td>Applicant’s time (months)</td>
<td>7.9</td>
<td>7.4</td>
<td>6.7</td>
<td>6.4</td>
<td>5</td>
</tr>
</tbody>
</table>

Note: Values indicate the data for approved applications that were filed in or after April 2004.
Review Time for New Drugs (2) (Priority Review Products)

【Target (Priority Review Products)】

(1) FY2001
- Total Review Time for New Drugs: 9 months (median)
  - Regulatory review time: 6 months
  - Applicant’s time: 3 months

(2) FY2010
- Total Review Time for New Drugs: 10 months (median)
  - Regulatory review time: 6 months
  - Applicant’s time: 4 months

【Median Total Review Time for New Drugs (Priority Review Products)】

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of approved applications</td>
<td>20</td>
<td>24</td>
<td>15</td>
<td>20(13)</td>
<td>—</td>
</tr>
<tr>
<td>Total review time (months)</td>
<td>12.3</td>
<td>15.4</td>
<td>11.9</td>
<td>9.2(12.0)</td>
<td>10</td>
</tr>
<tr>
<td>Regulatory review time (months)</td>
<td>4.9</td>
<td>7.3</td>
<td>3.6</td>
<td>4.9(5.3)</td>
<td>6</td>
</tr>
<tr>
<td>Applicant’s time (months)</td>
<td>6.5</td>
<td>6.8</td>
<td>6.4</td>
<td>3.4(6.0)</td>
<td>4</td>
</tr>
</tbody>
</table>

Note 1: Values indicate the data for approved applications that were filed in or after April 2004
Note 2: ( ) indicate the data for approved applications excluding of Mishoin-yaku approval
## Estimate of Drug Lag Time

<table>
<thead>
<tr>
<th>Lag</th>
<th>FY2006</th>
<th>FY2007</th>
<th>FY2008</th>
<th>FY2009</th>
<th>FY2010</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-Application</strong></td>
<td>1.2y</td>
<td>2.4y</td>
<td>1.5y</td>
<td>1.5y</td>
<td>(1.5y)</td>
</tr>
<tr>
<td><strong>In-Review</strong></td>
<td>1.2y</td>
<td>1.0y</td>
<td>0.7y</td>
<td>0.5y</td>
<td>(0.14y)</td>
</tr>
<tr>
<td><strong>Drug Lag</strong></td>
<td>2.4y</td>
<td>3.4y</td>
<td>2.2y</td>
<td>2.0y</td>
<td>(1.64y)</td>
</tr>
</tbody>
</table>

Note: Pre-Application Lag: Median years of difference b/w USA/Japan application for each product
IN-Review Lag: Median years of difference b/w Review time (USA/Japan) for each product approved in Japan
Drug Lag: Pre-application Lag + In-Review Lag
This is how we achieved the target

- Policy
- Human resources
- Consultation and Review
- Cooperation with Academia, Industry
New Growth Strategy (Cabinet decision in June 2010)

(2) Health power strategy through “Life Innovation”

Promoting research and development of innovative pharmaceuticals and medical and nursing care technologies from Japan

We will promote research and development of highly safe, superior, and innovative pharmaceuticals and medical and nursing care technologies from Japan. We will promote unified approaches among industry, government, and academia, foster drug development ventures, and promote research, development, and application in a number of fields. These include new drugs, regenerative medicine and other state-of-the-art medical technologies, remote medical treatment systems making full use of information and communications technologies, use of manufacturing technologies to improve personal mobility for the elderly, and medical and nursing care robots. To this end, we will work to resolve the urgent drug and device lag issue, improve the clinical testing environment, and expedite drug approval decisions.
Expansion of Workforce as 5 year strategy

対策

● 治験相談体制の拡充強化
  ー 人員の拡充
    ・新医薬品の審査・相談人員を倍増
  ー 治験相談の質・量の向上
    ・開発期間等の改善を促す助言
    ・企業の申請準備期間の短縮 等

● 審査体制の拡充強化
  ー 人員の拡充
    （同左）
  ー 審査業務の充実・改善
    ・申請前の事前評価システム導入
    による申請後の業務の効率化 等

● 承認審査のあり方や、基準の明確化
  ・国際共同治験や新技術に関する指針の作成 等

● 国際連携の強化
  ・FDA等海外規制当局との連携強化

対策

目標（平成23年度達成）

新医薬品の上市までの期間を2.5年（開発期間と審査期間をそれぞれ1.5年、1.0年）短縮することを目指す（平成19年度から5年間）
<table>
<thead>
<tr>
<th></th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>256</td>
<td>291</td>
<td>319</td>
<td>341</td>
<td>426</td>
<td>521</td>
<td>605</td>
<td>648</td>
</tr>
<tr>
<td><strong>Review Dept.</strong></td>
<td>154名</td>
<td>178名</td>
<td>197名</td>
<td>206名</td>
<td>277名</td>
<td>350名</td>
<td>389名</td>
<td>415名</td>
</tr>
<tr>
<td><strong>Safety Debt.</strong></td>
<td>29名</td>
<td>43名</td>
<td>49名</td>
<td>57名</td>
<td>65名</td>
<td>82名</td>
<td>123名</td>
<td>133名</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2013 (End of 2nd Mid-term plan)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>751 (planed)</td>
</tr>
</tbody>
</table>

PMDA Staff Size
(1) Prior Assessment Consultation

(2) Priority Review Products Estimate Consultation

(3) Sharing Review Progress

(4) Pharmaceutical Affairs Consultation on Research and Development Strategy

(5) Regulatory Science
What can we do and should we do?

Not only PMDA, but also “All Japan” ...
Thank you for your attention!