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

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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

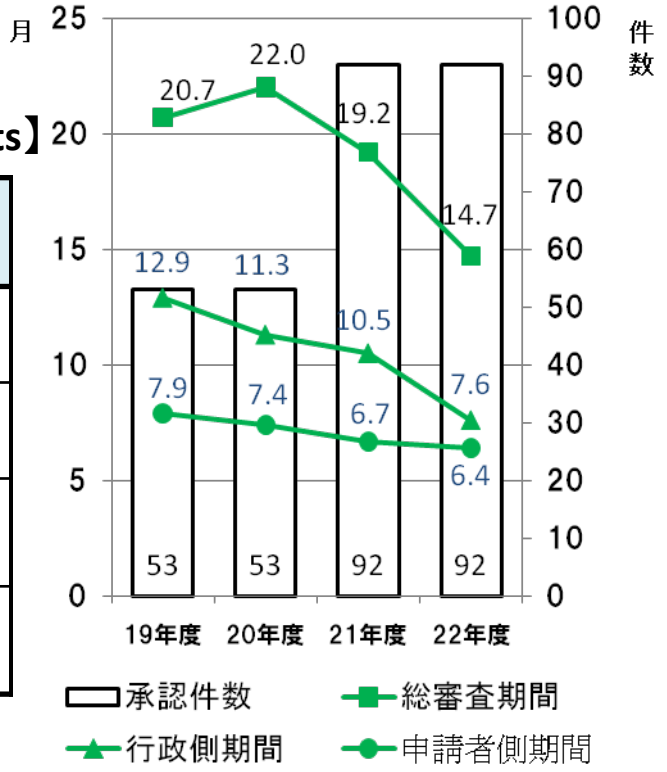
Total Review Time for New Drugs: 16 months (median)

- Regulatory review time: 11 months
- Applicant's time: 5 months

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

	FY2007	FY2008	FY2009	FY2010	Target (FY2010)
Number of approved applications	53	53	92	92	—
Total review time (months)	20.7	22.0	19.2	14.7	16
Regulatory review time (months)	12.9	11.3	10.5	7.6	11
Applicant's time (months)	7.9	7.4	6.7	6.4	5

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: 9months (median)

- **Regulatory review time: 6months**
- **Applicant's time: 3months**

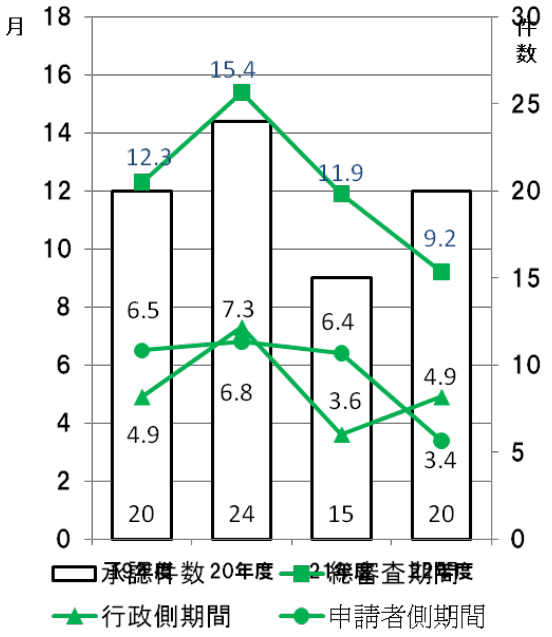
(2) FY2010

Total Review Time for New Drugs: 10months(median)

- **Regulatory review time: 6months**
- **Applicants time: 4months**

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

	FY2007	FY2008	FY2009	FY2010	Target (FY2010)
Number of approved applications	20	24	15	20(13)	—
Total review time (months)	12.3	15.4	11.9	9.2(12.0)	10
Regulatory review time (months)	4.9	7.3	3.6	4.9(5.3)	6
Applicant's time (months)	6.5	6.8	6.4	3.4(6.0)	4



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

Lag	FY2006	FY2007	FY2008	FY2009	FY2010
Pre-Application	1．2y	2．4y	1．5y	1．5y	(1．5y)
In-Review	1．2y	1．0y	0．7y	0．5y	(0.14y)
Drug Lag	2．4y	3．4y	2．2y	2．0y	(1．64y)

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

Policies

○ 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**.

New Growth Strategy

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

目標
（平成23年度達成）

- 開発から申請までの期間を1.5年短縮
- 申請から承認までの期間を1年間短縮

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）

PMDA Staff Size

	2004	2005	2006	2007	2008	2009	2010	2011	2013 (End of 2nd Mid-term plan)
Total	256	291	319	341	426	521	605	648	751 (planed)
Review Dept.	154名	178名	197名	206名	277名	350名	389名	415名	
Safety Debt.	29名	43名	49名	57名	65名	82名	123名	133名	

Topics

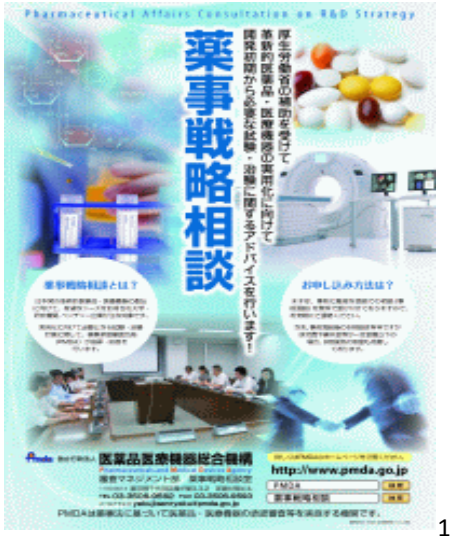
(1) Prior Assessment Consultation

(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 !