



# IMDRF

International Medical  
Device Regulators Forum

## New Direction of Japanese Regulations on MD/IVD

- Japan Update -





## Topics

- Collaboration plan to accelerate review of MDs
- Revision of Pharmaceutical Affairs Law (PAL); Implementation of PMD Act.



## Collaboration plan to accelerate review of MDs

(issued on 31 March 2014)

This plan from FY 2014 to FY 2018 aims to shorten and standardize the review periods of MD approval in cooperation with the Japanese regulatory authorities and industries by;

### 1. Taking measures to improve the quality of review process

Training for applicants, Efficient consultation service, Standardization of review process

### 2. Setting standard review periods

80<sup>th</sup> percentile value out of application cohorts should satisfy each targeted overall review period from MD application to its approval.

### 3. Managing progress of this plan

Regulatory authorities and industries will check its progress regularly and take necessary action(s) so that it works well.



## Standard review periods in the collaboration plan

80<sup>th</sup> percentile value out of application cohorts will satisfy the following targeted overall review period from MD application to its approval by end of FY2018;

1. Brand new medical device
  - Normal review process: 12 months
  - Priority review process: 9 months
2. Improved medical device
  - With clinical trial data: 9 months
  - Without clinical trial data: 7 months
3. “Me-too” medical device
  - New approval application: 5 months
  - Partial change approval application: 4 month

**Increase of reviewers with higher application fees will be needed.**



## (Ref.) Key achievements and further challenges of Action Program from FY 2009 to FY 2013

### Key Achievements

- Shortening review periods.
- Increasing the number of reviewers as well as enriching their training.
- Clarifying review standards and enhancing consultation service.
- Enhancing information disclosure.
- Accelerating certification of class II MD by registered certification body.
- Closely communicating between the regulatory authorities and industries.

### Further Challenges

- Improving the quality of review process involved by both reviewers and applicants.
- Shortening review periods.
- Promoting standardization of review periods.



## (Ref.) Action program to accelerate review of MDs

(from FY 2009 to FY 2013)

This program aimed to accelerate review of MD, based on efforts by the Japanese regulatory authorities and industries, by;

1. Increasing reviewers and enriching their training
2. Introducing a 3-track review system
3. Clarifying review standards
4. Taking other measures such as
  - Promotion of information disclosure
  - Progress management with regular meeting with stakeholders



## Collaboration plan to accelerate review of IVDs

(issued on 31 March 2014)

This plan from FY 2014 to FY 2018 aims to shorten and standardize the review periods of IVD approval in cooperation with the Japanese regulatory authorities and industries by;

### 1. Taking measures to improve the quality of review process

Training for applicants, Efficient consultation service, Standardization of review process

### 2. Setting standard review periods

80<sup>th</sup> percentile value out of application cohorts should satisfy each targeted overall review period from IVD application to its approval. (13 months for IVD with opinions from external experts and 7 months for normal IVD)

### 3. Increase of reviewers

### 4. Managing progress of this plan

Regulatory authorities and industries will check its progress regularly and take necessary action(s) so that it works well.



## Topics

- Collaboration plan to accelerate review of MDs
- Revision of Pharmaceutical Affairs Law (PAL); Implementation of PMD Act.





## For implementation of PMD Act:

- Authority and responsibility of Medical Device Evaluation Division in MHLW have been strengthened since July 2014.
- Relevant cabinet and ministerial ordinances as well as notifications were issued in July and August 2014.
- The amendment law is to be enforced on 25 November 2014.
- More details will be notified subsequently.



## (Ref.) PAL revision related information

- Revision of Pharmaceutical Affairs Law (PAL) was adopted by the Diet, and announced on 27 November 2013.
- Medical Device Development Promotion Act was announced on 27 June 2014.



## (Ref.) Summary of PAL revision

- Points of the amendment are to;
  1. Strengthen safety measures regarding drugs and medical devices
  2. Revise medical device regulations based on its characteristics
  3. Introduce Regenerative and Cellular Therapy Products (RCTP) & Gene Therapy Products (GTP) regulations based on their characteristics
- Name of PAL will be changed to  
“Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics” (, called “PMD Act”).
- The chapter for “Medical Device” will be prepared.



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# Thank you



MHLW



PMDA



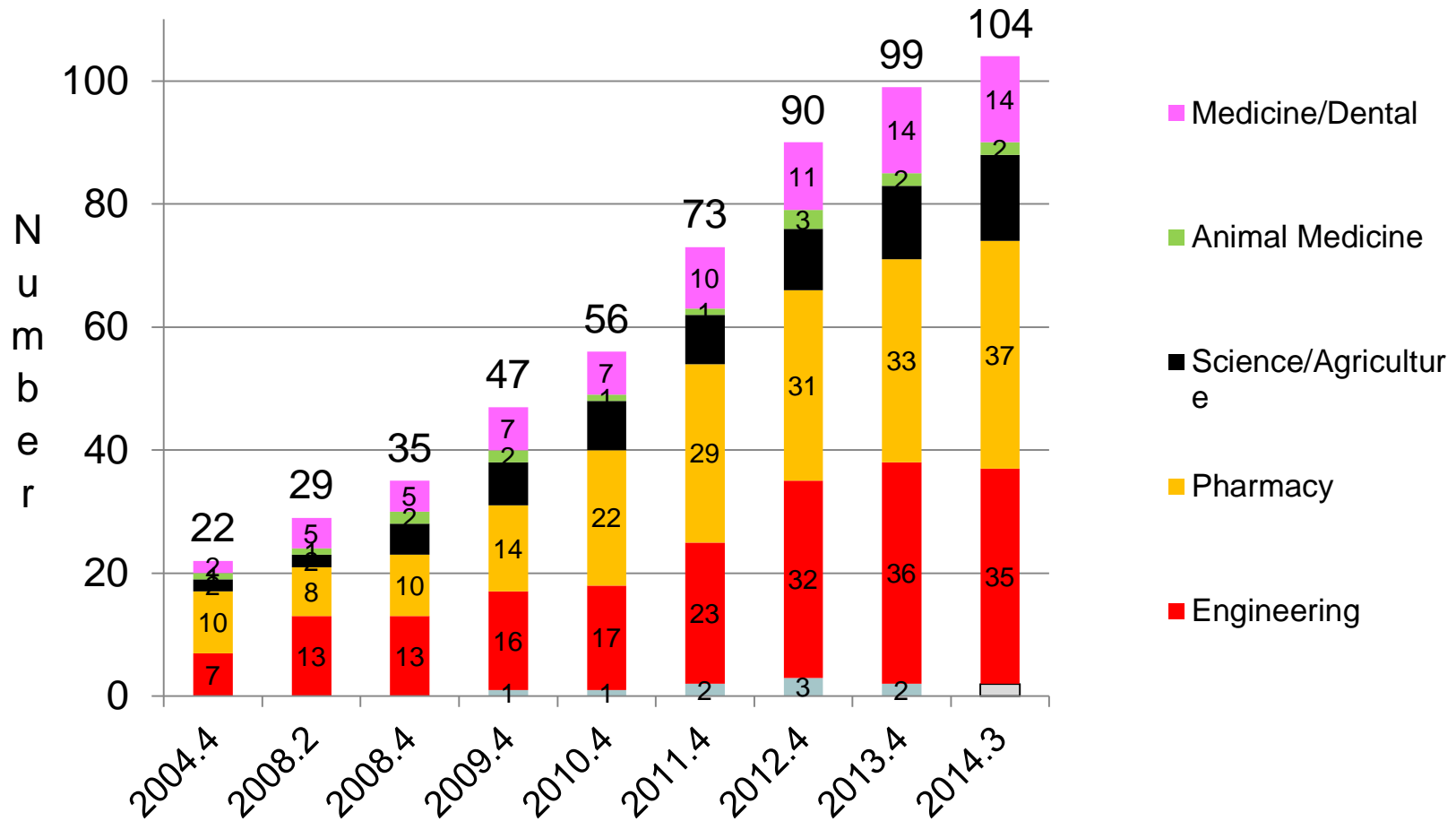
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# Statistics



## Number of reviewers – increasing





## Number of MD approvals – stable

Class	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013
I	1	-	-	-	-
II	1,123	554	196	143	131
III	616	756	671	847	830
IV	295	324	360	545	386
Total	2,035	1,634	1,227	1,535	1,347

### Number of certifications by registered certification bodies

Certification	2,313	2,158	2,393	2,442	2,200
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## Number and review time of brand new MDs – improving

### Priority items

FY	2006	2007	2008	2009	2010	2011	2012	2013
Goal (months)	—	—	—	—	16	16	15	13
Performance (months)	—	14.2	15.7	28.8	13.9	15.1	4.3	9.3
#	—	1	4	4	3	3	6	5

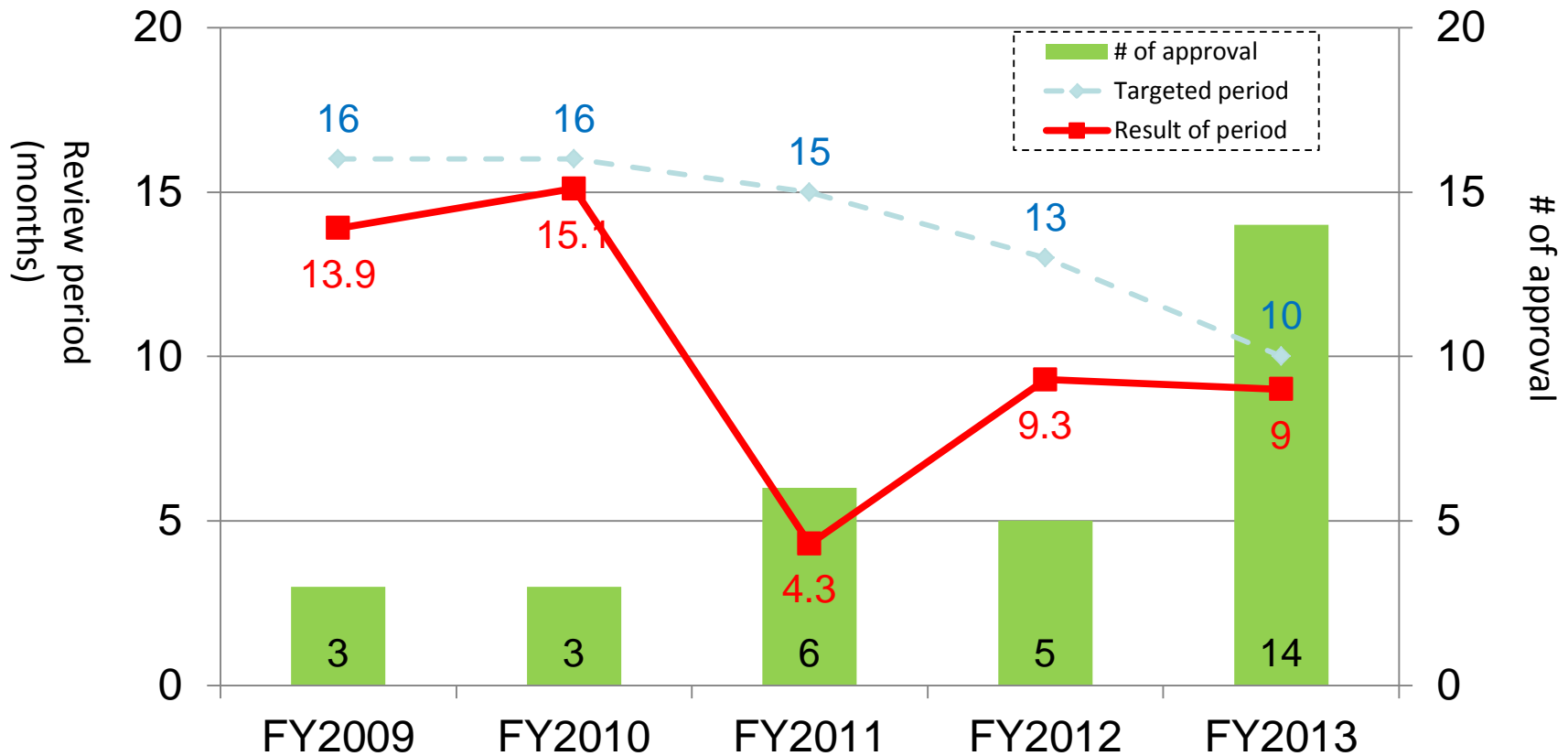
### Normal items

FY	2006	2007	2008	2009	2010	2011	2012	2013
Goal (months)	—	—	—	—	21	21	20	17
Performance (months)	10.3	15.7	15.1	14.4	11.0	16.5	9.7	12.7
#	5	14	19	12	33	15	27	41 16





## Brand new MD in priority process – targeted periods were satisfied

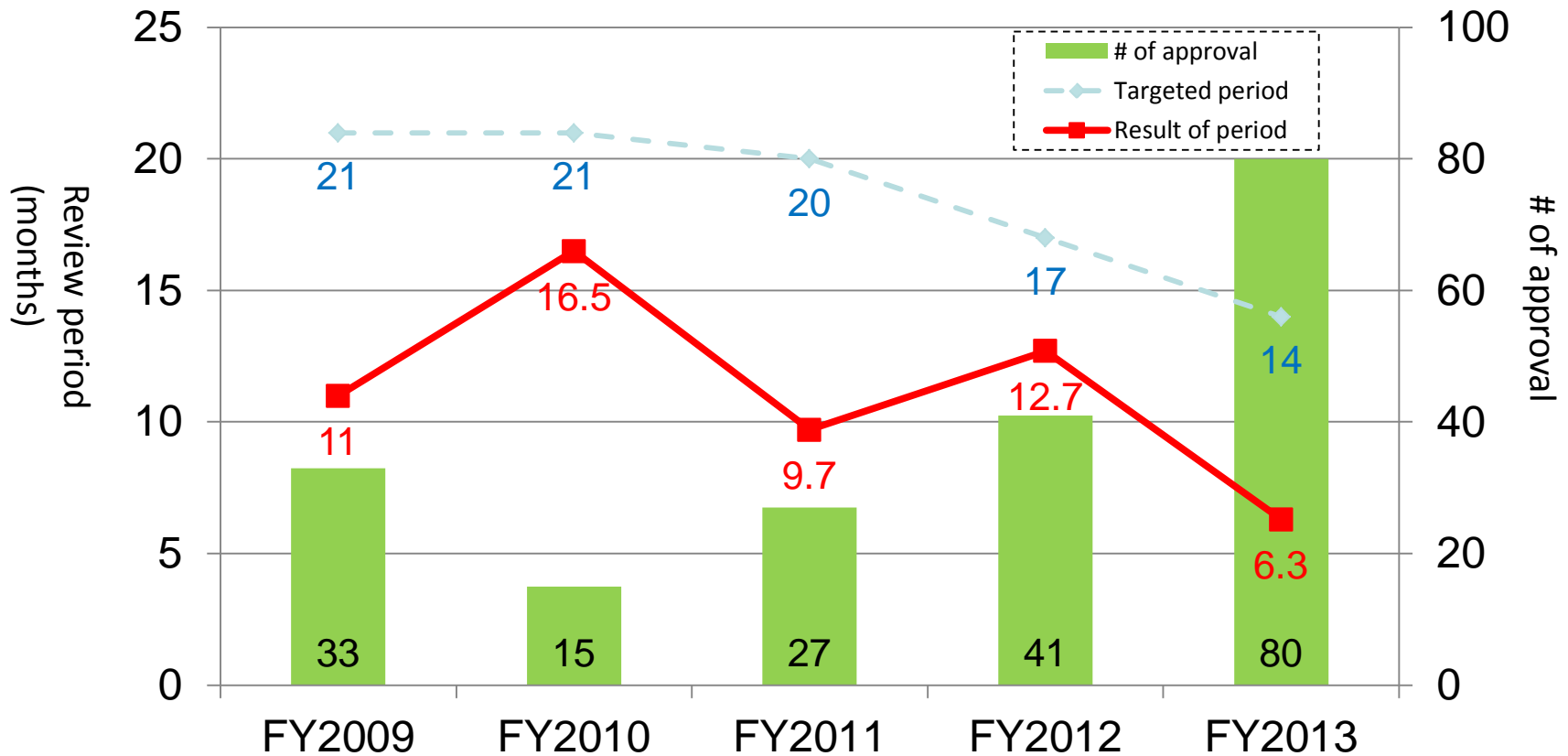


\* Targets are approved MDs for which application was made from FY2004 onward. review period (record) is median value of approval cohort.

\* Source: PMDA Annual Report (FY 2013)



## Brand new MD in normal process – targeted periods were satisfied

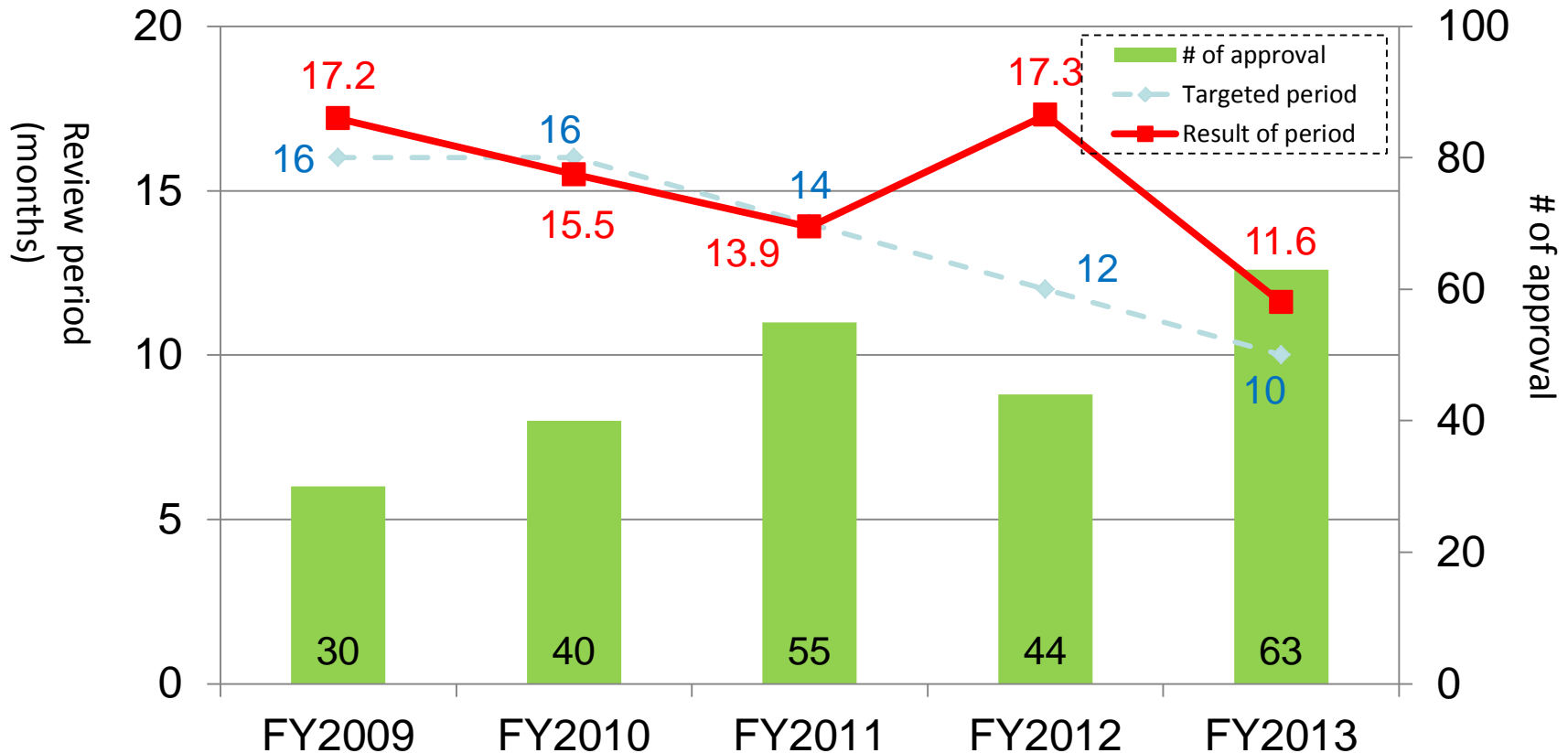


\* Targets are approved MDs for which application was made from FY2004 onward. review period (record) is median value of approval cohort.

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## Improved MD with clinical data – some targeted periods were not satisfied due to review of many earlier applications

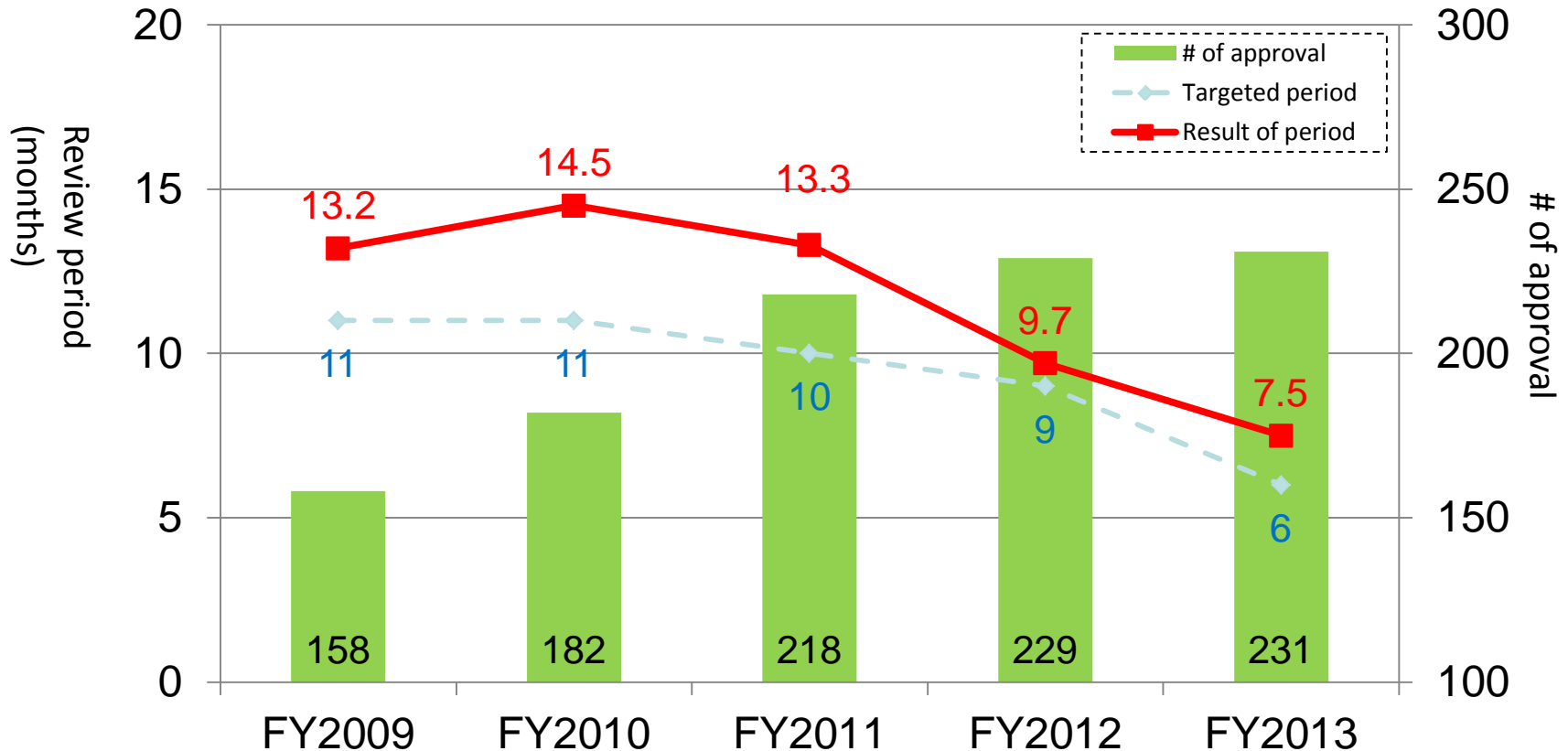


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## Improved MD without clinical data – Any targeted periods were not satisfied due to review of many earlier applications

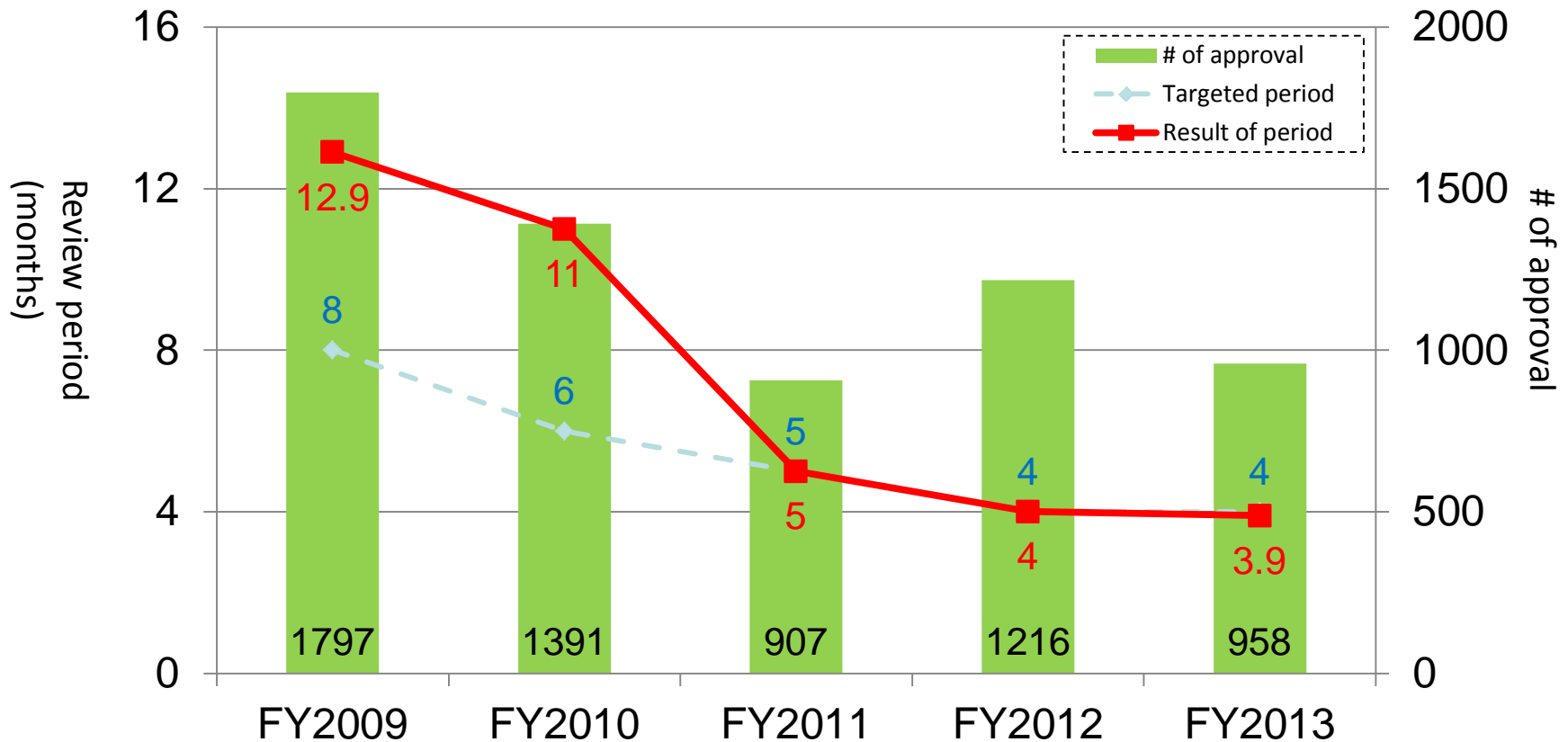


\* Targets are approved MDs for which application was made from FY2004 onward. review period (record) is median value of approval cohort.

\* Source: PMDA Annual Report (FY 2013)



## “Me-too” MD – targeted periods were not satisfied since FY 2011



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\* Source: PMDA Annual Report (FY 2013)